SLOVENSKI STANDARD
SIST EN 302 537-1 V1.1.2:2008

01-september-2008

Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) - Službeni sistemi ultra majhnih moļi za medicinske podatke, ki delujejo v frekvenļnih območjih od 401 MHz do 402 MHz in od 405 MHz do 406 MHz - 1. del: Tehniļne karakteristike in preskusne metode

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

Ta slovenski standard je istoveten z: **EN 302 537-1 Version 1.1.2**

ICS:

33.060.99	Druga oprema za radijske komunikacije	Other equipment for radiocommunications
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

SIST EN 302 537-1 V1.1.2:2008 **en**

ETSI EN 302 537-1 V1.1.2 (2007-12)

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 1: Technical characteristics and test methods

Reference
DEN/ERM-TG30-005-1

Keywords
health, SRD

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

Important notice

Individual copies of the present document can be downloaded from:
http://www.etsi.org

The present document may be made available in more than one electronic version or in print. In any case of existing or perceived difference in contents between such versions, the reference version is the Portable Document Format (PDF). In case of dispute, the reference shall be the printing on ETSI printers of the PDF version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status. Information on the current status of this and other ETSI documents is available at
http://portal.etsi.org/tb/status/status.asp

If you find errors in the present document, please send your comment to one of the following services:
http://portal.etsi.org/chaircor/ETSI_support.asp

Copyright Notification

Contents

Intellectual Property Rights 6
Foreword 6
Introduction 7
1 Scope 8
2 References 9
2.1 Normative references 9
2.2 Informative references 9
3 Definitions, symbols and abbreviations 10
3.1 Definitions 10
3.2 Symbols 12
3.3 Abbreviations 13
4 Technical requirements and specifications 13
4.1 General requirements 13
4.1.1 Transmitter requirements 13
4.1.2 Receiver requirements 13
4.1.3 Spectrum access requirements 13
4.2 Presentation of equipment for testing purposes 13
4.2.1 Choice of model for testing 14
4.2.2 Testing of equipment with alternative power levels 14
4.2.3 Testing of equipment that does not have an external 50 Ω RF connector (integral antenna equipment) 14
4.2.3.1 Equipment with an internal permanent or temporary antenna connector 14
4.2.3.2 Equipment with a temporary antenna connector 14
4.2.3.3 Equipment intended to be implanted in or worn on but totally external to a human body 15
4.3 Mechanical and electrical design 15
4.3.1 General 15
4.3.2 Controls 15
4.3.3 Transmitter shut-off facility 15
4.3.4 Marking 15
4.3.5 Equipment identification 15
4.4 Declarations by the provider 15
4.5 Auxiliary test equipment 15
4.6 Interpretation of the measurement results 16
5 Test conditions, power sources and ambient temperatures 16
5.1 Normal and extreme test conditions 16
5.2 Test power source 16
5.2.1 External test power source 16
5.2.2 Internal test power source 17
5.3 Normal test conditions 17
5.3.1 Normal temperature and humidity 17
5.3.2 Normal test power source 17
5.3.2.1 Mains voltage 17
5.3.2.2 Regulated lead-acid battery power sources 17
5.3.2.3 Other power sources 17
5.4 Extreme test conditions 18
5.4.1 Extreme temperatures 18
5.4.1.1 Procedure for tests at extreme temperatures 18
5.4.1.1.1 Procedure for equipment designed for continuous operation 18
5.4.1.1.2 Procedure for equipment designed for intermittent operation 18
5.4.1.2 Extreme temperature ranges 19
5.4.2 Extreme test source voltages 19
5.4.2.1 Mains voltage 19
5.4.2.2 Regulated lead-acid battery power sources 19

5.4.2.3 Power sources using other types of batteries....19
5.4.2.4 Other power sources....20

6 General conditions....20
6.1 Normal test signals and test modulation....20
6.1.1 Normal modulation test signals for data....20
6.2 Antennas....20
6.3 Artificial antenna....20
6.3.1 Artificial antenna for transmitters with 50 Ω impedance connector....20
6.4 Test fixture for ULP-AMD, ULP-AMD-P and ULP-AMI-P devices....21
6.5 Test fixture for ULP-AMI and ULP-BWD....21
6.6 Test sites and general arrangements for radiated measurements....21
6.7 Modes of operation of the transmitter....22
6.8 Measuring receiver....22

7 Measurement uncertainty....22

8 Methods of measurement and limits for transmitter parameters....23
8.1 Frequency error....23
8.1.1 Definition....24
8.1.1.1 Method of measurement for systems with an unmodulated carrier frequency provision....24
8.1.1.2 Method of measurement for systems with a modulated carrier frequency....24
8.1.2 Limit....24
8.2 Emission bandwidth measurement....25
8.2.1 Definition....25
8.2.1.1 Method of measurement....25
8.2.2 Limits....25
8.3 Effective radiated power of the fundamental emission....25
8.3.1 Definition....26
8.3.1.1 Methods of measurement....26
8.3.2 Limit as a function of spectrum access method....26
8.3.2.1 Limit for systems using LBT and AFA for spectrum access....27
8.3.2.2 Limit for devices using low duty cycle and low power for spectrum access....27
8.4 Spurious emissions....27
8.4.1 Definition....27
8.4.1.1 Method of measuring the effective radiated power of spurious emissions....27
8.4.2 Limits....28
8.5 Frequency stability under low voltage conditions....28
8.5.1 Definition....28
8.5.1.1 Method of measurement....28
8.5.2 Limits....29
8.6 Spectrum access based on low power and low duty cycle....29
8.6.1 Definition....29
8.6.1.1 Methods of measurement....29
8.6.2 Limits....30
8.6.2.1 Duty cycle limit....30
8.6.2.2 Repetitive transmission within an hour....30

9 Methods of measurement and limits for receiver parameters....30
9.1 Spurious radiation....30
9.1.1 Definition....31
9.1.1.1 Method of measuring the effective radiated power of spurious radiations....31
9.1.2 Limits....31

10 Requirements for spectrum access and measuring methods for monitoring systems using LBT and AFA....32
10.1 Purpose....32
10.2 LBT threshold power level....32
10.2.1 Measurement method using out-of-operating-region interference....33
10.2.2 Measurement method using frequency administration commands....34
10.2.3 Results based on above test method....34
10.3 Monitoring system bandwidth....34
10.3.1 Measurement method using out-of-operating-region interference....34

10.3.2 Measurement method using frequency administration commands 35
10.3.3 Results based on above test method....35
10.4 Monitoring system scan cycle time and minimum channel monitoring period....35
10.4.1 Measurement method using out-of-operating-region interference....35
10.4.1.1 Scan cycle time 35
10.4.1.2 Minimum channel monitoring period 36
10.4.2 Measurement method using frequency administration commands 36
10.4.3 Results based on above test method....36
10.4.3.1 Scan cycle time 36
10.4.3.2 Minimum Channel Monitoring Period....37
10.5 Channel access based on ambient levels relative to the calculated access LBT threshold level, P_{Th} 37
10.5.1 Access based on lowest ambient level above P_{Th} using out-of-operating-region interference....37
10.5.2 Access based on lowest ambient level above P_{Th} using frequency administration commands 38
10.5.3 Results based on above test method....38
10.6 Discontinuation of MEDS session if a silent period greater than or equal to 5 s occurs....38
10.6.1 Measurement method....38
10.6.2 Results based on above test method....38
10.7 Use of pre-scanned alternate channel 39
10.7.1 Measurement method for alternate channel selection using out-of-operating-region interference 39
10.7.2 Measurement method for alternate channel selection using frequency administration commands 40
10.7.3 Results based on above test method....40

Annex A (normative): Radiated measurements 42

A.1 Test sites and general arrangements for measurements involving the use of radiated fields 42
A.1.1 Outdoor test site 42
A.1.1.1 Standard position....43
A.1.1.2 Equipment in close proximity to the human body but external to it 43
A.1.1.3 Human torso simulator for ULP-BWD and ULP-AMI....43
A.1.2 Test antenna....44
A.1.3 Substitution antenna 44
A.1.4 Optional additional indoor site 45

A.2 Guidance on the use of radiation test sites....45
A.2.1 Measuring distance....46
A.2.2 Test antenna....46
A.2.3 Substitution antenna 46
A.2.4 Artificial antenna....46
A.2.5 Auxiliary cables....46

A.3 Further optional alternative indoor test site using a fully anechoic chamber....46
A.3.1 Example of the construction of a fully anechoic chamber....47
A.3.2 Influence of parasitic reflections in fully anechoic chambers 47
A.3.3 Calibration of the fully anechoic chamber 47

Annex B (normative): Technical performance of the spectrum analyser....50

Annex C (informative): Bibliography....51

History....52

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: *"Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards"*, which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (http://webapp.etsi.org/IPR/home.asp).

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 European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

For non EU countries the present document may be used for regulatory purposes.

The present document is part 1 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 [10] and Active Medical Implants and Peripherals the medical section of which is regulated under the Active Implantable Medical Device Directive [11] and the radio part of which are regulated under the R&TTE Directive [8], 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 2008

Introduction

The present document covers the ultra low power radio transmitters used in a new Medical Data Service and the various types of devices that form part of the system providing the service. It includes methods of measurement and requirements for radio systems used in the service that are fitted with an antenna connector and/or having an integral antenna. If a device which is operating in the MEDS and is available on the market is required to be checked, it should be tested in accordance with the methods of measurement specified in the present document.

- Clauses 1 through 3 provide a general description on the types of equipment covered by the present document and the definitions and abbreviations used.
- Clause 4 provides a guide to essential requirements, the number of samples required in order that tests may be carried out and any markings on the equipment that the provider has to supply.
- Clauses 5 and 6 provide general test conditions to be used.
- Clause 7 gives the maximum measurement uncertainty values.
- Clauses 8, 9 and 10 specify the spectrum utilization parameters. Clause 8 specifies low power low duty cycle spectrum access technical parameters. Clause 9 specifies receiver technical requirements. Clause 10 specifies methods of spectrum access that are required to be implemented in order to gain access to the available spectrum. In particular clause 10.2 and subsequent clauses describe specifications that have been chosen to minimize harmful interference to other equipment or services and reduce the potential for interference to this equipment from ambient sources based on use of LBT and AFA.
- Annex A (normative) provides specifications concerning radiated measurements.
- Annex B (normative) provides specifications for test equipment.
- Annex C (informative) bibliography; provides additional information.

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 who will use the data to diagnose and/or 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 (MDD) [10] or the Active Implantable Medical Device Directive (AIMD) [11]. 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 sensors or handheld devices that are intended to operate in very close proximity to the human body, including touching the body, the radio antenna of which 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 [9] 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.

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 TR 100 028 (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[2] ITU-T Recommendation O.153 (1992): "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[3] CISPR 16-2-3 (2003): "Specification for radio disturbance and immunity measuring apparatus and methods. Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".

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

[5] ANSI C63.17 (1998): "American National Standard for Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (UPCS) Devices".

2.2 Informative references

[6] ETSI EN 302 537-2: "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".

[7] G. Hartsgrove, A. Kraszewski, and A. Surowiec: "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies", as published in Bioelectromagnetics 8:29-36 (1987).

[8] 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).

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

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

[11] 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 (AIMD Directive).

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and definitions apply:

access protocol: specification for measuring natural and man-made ambient background levels for the purpose of providing a technique for spectrum access that reduces the potential for harmful interference to/from other users of the spectrum

Active Medical Device (AMD): any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

Active Implantable Medical Device (AIMD): any active medical device (AMD) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Adaptive Frequency Agility (AFA): ability to determine an unoccupied sub-band or channel of operation in order to minimize interference with other users of the same band

artificial antenna: reduced-radiating dummy load equal to the nominal impedance specified by the provider

Body Worn Device (BWD): a medical sensor, handheld device, or other medical device intended to be operated in close proximity to the human body, and is used to sense and/or transfer, via means of radio frequency transmission, human physiological parameters or system programming information

conducted measurements: measurements that are made using a direct 50 Ω connection to the equipment under test

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

emission bandwidth: measured as the width of the signal between the points on either side of carrier centre frequency that are 20 dB down relative to the maximum level of the modulated carrier

NOTE: Compliance is determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1 % of the emission bandwidth of the device under test.

integral antenna: permanent fixed antenna, which may be built-in, designed as an indispensable part of the equipment

LBT threshold power level: ambient signal power level above which the monitoring system selects spectrum for use in a communication session according to the next available channel with the lowest level of ambient signal power or least interfered channel (LIC)

Least Interfered Channel (LIC): channel, among the available channels, that has the lowest potential for causing interference to or receiving interference from other users of the band

Listen Before Talk (LBT): combination of the listen mode followed by the talk mode

listen mode: action taken by an interrogator to detect an unoccupied sub-band or channel

Medical Data Service (MEDS): service that uses a system specifically for the purpose of providing non-voice digital communications between active medical implants and/or body worn devices and other devices external to the human body engaged in transferring non-time critical individual patient related physiological information

Medical Data Service (MEDS) communication session: collection of transmissions that may or may not be continuous, between co-operating ULP-AMI, ULP-AMI-P, ULP-BWD, ULP-AMD and ULP-AMD-P

Medical Data Service (MEDS) system: collection of medical devices having short range RF transmitting capability, that are associated with a specific patient, consisting of at least one active medical implant or body worn device together with other devices external to the body, that have the ability to communicate with each other using frequencies in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz bands

Medical Data Service (MEDS) System Communication Link (MEDSCL): collection of transmissions that may or may not be continuous, between MEDS system devices including at least one active medical implant or body worn device together with other devices external to the body engaged in transferring non-time critical patient related physiological information collected by a single MEDS system

Medical Device (MD): any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the provider to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means.

Medical Data Service (MEDS) System Communication Channel: any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MEDS session

NOTE: As stated in CEPT/ERC/REC 70-03 [9], annex 12 Bands a1 and a2, it is permitted to aggregate 25 kHz segments up to a maximum of 100 kHz for each channel bandwidth.

Medical Data Service (MEDS) System Device: Any ultra low power medical device transmitting in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz band. Only two types of MEDS system devices are permitted under the present document:

1) Frequency agile devices designed to access a minimum of 18 channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands with a minimum of 9 channels defined for each 1 MHz segment (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz).

2) Devices capable of operation only on a single channel using low duty cycle and low power for spectrum access in the 401 MHz to 402 MHz or 405 MHz to 406 MHz bands, see clause 8.6 and the following clauses.

monitoring system: circuitry in an active medical device that assures conformity with the spectrum access protocol requirements based on Listen before Talk for channel selection and Adaptive Frequency Agility to access the channel selected by the LBT process for operation

provider: manufacturer or person responsible for placing the apparatus on the market

NOTE: See R&TTE Directive [8], article 6.3.

radiated measurements: measurements which involve the absolute measurement of a radiated field

talk mode: transmission of intentional radiation by a transmitter

telecommand: use of radio communication for the transmission of signals to initiate, modify or terminate functions of equipment at a distance

telemetry: use of radio communication for indicating or recording data at a distance

time-critical data: data which if not transferred immediately will result in compromising the health and/or safety of the patient

Ultra Low Power Active Medical Implant (ULP-AMI): the radio part of any active medical device (AMD), which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

NOTE: The medical function of such device is regulated under the AIMD Directive [11]. The radio function of such device is regulated under the R&TTE Directive [8].

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P) device: the radio part of medical equipment outside the human body that communicates with an ULP-AMI, ULP-AMD, ULP-BWD, or other ULP-AMI-P to establish a Medical Data Service (MEDS) System Communication Link

NOTE: The medical function of such device is regulated under the AIMD Directive [11]. The radio function of such device is regulated under the R&TTE Directive [8].

Ultra Low Power Active Medical Device (ULP-AMD): the radio part of any active medical device (AMD) outside the human body which has its radio antenna external to the body and is used to communicate with a device that is part of a MEDS system

NOTE: The medical function of such device is regulated under the AIMD Directive [11] or Medical Device Directive [10], as appropriate for its intended use. The radio function of such device is regulated under the R&TTE Directive [8].

Ultra Low Power Active Medical Device Peripheral (ULP-AMD-P): the radio part of medical equipment outside the human body that communicates with an ULP-AMD, ULP-BWD, or other ULP-AMD-P to establish a Medical Data Service (MEDS) System Communication Link

NOTE: The medical function of such device is regulated under the Medical Device Directive [10]. The radio function of such device is regulated under the R&TTE Directive [8].

Ultra Low Power Body Worn Device (ULP-BWD): the radio part of a medical device, such as a physiological parameter sensor or handheld device, that is intended to operate in proximity to the human body (6 cm or less from the skin surface) which has its radio antenna external to the body and is used to communicate with a device that is part of a MEDS system

NOTE: The medical function of such device is regulated under the AIMD Directive [11] or Medical Device Directive [10], as appropriate for its intended use. The radio function of such device is regulated under the R&TTE Directive [8].

3.2 Symbols

For the purposes of the present document, the following symbols apply:

B	bandwidth
dB	decibel
dBm	decibel relative to 1mWatt
E	electrical field strength
Eo	reference electrical field strength (see annex A)
f	frequency
f_c	channel centre frequency
f_e	frequency under extreme conditions
G	Antenna Gain
NaCl	sodium chloride
P	power
R	distance
Ro	Reference distance (see annex A)
P_{Th}	maximum threshold power level (see clause 10)
t	time
V	Volt
W	Watt
λ	wavelength

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
AMD	Active Medical Device
BWD	Body Worn Device
CW	Continuous Wave
e.r.p.	effective radiated power
EUT	Equipment Under Test
FDD	Frequency Division Duplex
LBT	Listen Before Talk
LDC	Low Duty Cycle
LIC	Least Interfered Channel

NOTE: See definitions.

MD	Medical Device
MEDSCL	Medical Data Service System Communication Link
MEDS	Medical Data Service
OATS	Open Area Test Site
RF	Radio Frequency
SRD	Short Range Device
TDD	Time Division Duplex
ULP-AMD	Ultra Low Power Active Medical Device
ULP-AMD-P	Ultra Low Power Active Medical Device Peripheral to ULP - BWD
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral
ULP-BWD	Ultra Low Power Body Worn Device
VSWR	Voltage Standing Wave Ratio

4 Technical requirements and specifications

4.1 General requirements

4.1.1 Transmitter requirements

See clause 8 for requirements and measurement procedures.

4.1.2 Receiver requirements

See clause 9 for requirements and measurement procedures.

4.1.3 Spectrum access requirements

See clause 10 for requirements and measurement procedures for accessing spectrum.

4.2 Presentation of equipment for testing purposes

Each equipment submitted for testing shall fulfil the requirements of the present document on all frequencies over which it is intended to operate. Compliance with this requirement should be shown by testing each unit on a frequency near the mid point of the 401 MHz to 402 MHz and 405 MHz to 406 MHz as applicable.