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Ultra Low Power Medical Data Service (MEDS)
Systems operating in the frequency range
401 MHz to 402 MHz and 405 MHz to 406 MHz;
Harmonised Standard covering the essential requirements
of article 3.2 of the Directive 2014/53/EU

Reference

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Foreword

This draft Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the combined Public Enquiry and Vote phase of the ETSI standards EN Approval Procedure.

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.11] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.2].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
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Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

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Introduction

The present document covers the ultra low power radio devices used in a 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.

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.

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 primary users of the band.

The present document is a specific product standard applicable to ultra low power devices that are part of a MEDS system operating in spectrum within the frequency bands 401 MHz to 402 MHz and 405 MHz to 406 MHz.

The frequency usage conditions for the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz are European wide harmonised for "active medical implant devices" according to Commission Implementing Decision 2013/752/EU [i.12] and ERC Decision (01)17 [i.1].

The present document contains the technical characteristics for ultra low power radio equipment and is structured in the following way:

- Clauses 1 through 3 provide a general description on the types of equipment covered by the present document and the definitions, symbols and abbreviations used.
- Clause 4 provides the technical requirements, specifications, limits and conformance relative to transmitter, receiver, and spectrum access.
- Clauses 5.1 and 5.2 specify the conditions for testing of the equipment and interpretation of the measurement results with the maximum measurement uncertainty values.
- Clause 5.3 specifies the required measurement methods. In particular clause 5.3.8 describes the monitoring system performance specifications that have been chosen to minimize harmful interference to other equipment or services and minimize the potential for disturbance to this equipment from ambient sources or other medical device users in the band.
- Annex A (normative) provides the relationship between the present document and the essential requirements of Directive 2014/53/EU.
- Annex B (normative) provides specifications concerning radiated measurements.
- Annex C (normative) provides Technical performance of the spectrum analyser.
- Annex D (informative) bibliography provides additional information.

1 Scope

The present document 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 a MEDS service for telecommand and telemetry between devices that are part of a MEDS (see definition of MEDS);

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 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 4.2.3.1.2 and the following clauses.

The frequency usage conditions for the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz are European wide harmonised for "active medical implant devices" according to Commission Implementing Decision 2013/752/EU [i.12] and ERC Decision (01)17 [i.1] with the following usage restrictions:

- "This set of usage conditions is only available for systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and/or body-worn devices and other devices external to the human body used for transferring non-time critical individual patient-related physiological information."

The present document covers devices utilizing ultra low power radio devices in combination with medical devices, the medical portion of which is regulated by the Medical Device Directive [i.8] (MDD) or the Active Implantable Medical Device Directive (AIMD [i.9]). 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).

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.

The present document contains requirements to demonstrate that Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz "*… shall be so constructed that they both effectively use and support the efficient use of radio spectrum in order to avoid harmful interference*" (article 3.2 of the Directive 2014/53/EU [i.2]). It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

2 References

2.1 Normative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

Referenced documents which are not found to be publicly available in the expected location might be found at https://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.

The following referenced documents are necessary for the application of the present document.

[1] CISPR 16-2-3:2010+AMD1:2010+AMD2:2014: "Specification for radio disturbance and immunity measuring apparatus and methods. Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] ERC Decision (01)17 (2011 amendment): "Harmonised frequencies, technical characteristics and exemption from individual licensing of Ultra Low Power Active Medical Implant (ULP-AMI) communication systems operating in the frequency band 401 - 406 MHz on a secondary basis".

[i.2] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

[i.3] ETSI TR 100 028 (all parts) (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[i.4] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.5] "Radiofrequency Radiation Dosimetry Handbook" (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

[i.6] ANSI C63.17 (1998): "American National Standard for Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (UPCS) Devices".

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

[i.8] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MD Directive).

[i.9] 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).

[i.10] Recommendation ITU-R RS.1346: "Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz".

[i.11] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.12] Commission Implementing Decision 2013/752/EU of 11 December 2013 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices and repealing Decision 2005/928/EC.

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): 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

effective radiated power: maximum power radiated during the interval of continuous transmission within the emission bandwidth of the EUT with the highest radiated power in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate

NOTE: See clause 4.2.1.3.1.

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 communication 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 1: Aggregation of adjacent channels up to a maximum of 100 kHz channel for a single system is permitted.

NOTE 2: As stated in Commission Implementing Decision 2013/752/EU [i.12] and ERC Decision (01)17 [i.1], it is permitted to combine adjacent channels for increased bandwidth up to 100 kHz for each single system channel bandwidth.

Medical Data Service (MEDS) System Device: any ultra low power medical device communicating in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz band

NOTE: 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), see clause 4.2.3.1.1 and the following clauses.

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 4.2.3.1.2 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

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): 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 [i.9]. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P) device: 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 [i.9]. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

Ultra Low Power Active Medical Device (ULP-AMD): 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 [i.9] or Medical Device Directive [i.8], as appropriate for its intended use. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

Ultra Low Power Active Medical Device Peripheral (ULP-AMD-P): 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 [i.8]. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

Ultra Low Power Body Worn Device (ULP-BWD): 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 [i.9] or Medical Device Directive [i.8], as appropriate for its intended use. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

3.2 Symbols

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

B	bandwidth
B_{lf}	low frequency band edge (see clause 5.3.8.1.0)
B_{hf}	high frequency band edge (see clause 5.3.8.1.0)
dB	decibel
dBm	decibel relative to 1 mWatt
E	electrical field strength
Eo	reference electrical field strength (see annex B)
f	frequency
f_c	channel centre frequency
f_e	frequency under extreme conditions
G	Antenna Gain
Mc	Number of pulses captured during the one hour time sweep (see clause 5.3.8.2.1)
NaCl	sodium chloride
P	power
R	distance
Ro	Reference distance (see annex B)
P_{Th}	maximum threshold power level (see clause 4.2.3.1.1.2)
t	time
T_t	Total time of transmission during one hour for each mode of activation (see clause 5.3.8.2.1)

T_c	Total time of transmission during an hour with all modes activated (see clause 5.3.8.2.1)
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
CISPR	Comité International Spécial des Perturbations Radioélectriques
CW	Continuous Wave
e.r.p.	effective radiated power
EC	European Commission
EFTA	European Free Trade Association
ERC	European Radiocommunications Committee
EU	European Union
EUT	Equipment Under Test
FDD	Frequency Division Duplex
ITU-R	ITU Radiocommunication Sector
LBT	Listen Before Talk
LDC	Low Duty Cycle
LIC	Least Interfered Channel
LP/LDC	Low Power/Low Duty Cycle
MD	Medical Device
MDD	Medical Device Directive
MEDS	Medical Data Service
MEDSCL	Medical Data Service System Communication Link
OATS	Open Area Test Site
RF	Radio Frequency
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 specifications

4.1 Environmental profile

The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the declared operational environmental profile.