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STN	**Systémy zdravotníckej dátovej služby s ultranízkym výkonom (MEDS) pracujúce vo frekvenčnom rozsahu od 401 MHz do 402 MHz a od 405 MHz do 406 MHz. Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice 2014/53/EÚ.**	**STN EN 302 537 V2.1.1** 87 2537

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/17

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Ultra Low Power Medical Data Service (MEDS)
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Harmonised Standard covering the essential requirements
of article 3.2 of the Directive 2014/53/EU

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Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

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.

National transposition dates	
Date of adoption of this EN:	12 September 2016
Date of latest announcement of this EN (doa):	31 December 2016
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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).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

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.