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Short Range Devices (SRD);
Low Power Active Medical Implants (LP-AMI)
and associated Peripherals (LP-AMI-P)
operating in the frequency range 2 483,5 MHz to 2 500 MHz;
Harmonised Standard covering the essential requirements
of article 3.2 of the Directive 2014/53/EU

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Contents

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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.12] 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.1].

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.

The present document covers Low Power Active Medical Implants (LP-AMI) and associated Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz as described in the systems reference document for the equipment, ETSI TR 102 655 [i.2].

National transposition dates	
Date of adoption of this EN:	12 September 2016
Date of latest announcement of this EN (doa):	31 December 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 June 2017
Date of withdrawal of any conflicting National Standard (dow):	30 June 2018

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 is part of a set of standards developed by ETSI and is designed to fit in a modular structure to cover all radio and telecommunications terminal equipment within the scope of the Radio Equipment Directive (RE-D) [i.1]. The modular structure is shown in ETSI EG 201 399 [i.4].

LP-AMI/LP-AMI-P equipment in the AMICS is a unique technology using the frequency band 2 483,5 MHz to 2 500 MHz, that will provide for example high speed communications capability between individuals with AIMDs and medical practitioners engaged in utilizing these AIMDs for the purposes of diagnosing and delivering therapy to individuals with various illnesses. Equipment in the AMICS consists of LP-AMI and/or LP-AMI-P that provide human therapeutic and diagnostic data storage and analysis capability.

The present document includes methods of measurement for Low Power Active Medical Implants (LP-AMI), and Peripherals (LP-AMI-P), fitted with antenna connector and/or integral antenna. Equipment designed for use with an integral antenna may be supplied with a temporary or permanent internal connector for the purpose of testing, providing the characteristics being measured are not expected to be affected.

The frequency usage conditions for the bands 2 483,5 MHz to 2 500 MHz are European wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.13].

If equipment, which 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 is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms and symbols and abbreviations used.
- Clause 4 specifies the requirements and limits relative to transmitter, receiver, and spectrum access. The latter are primarily designed to minimize the possibility of disturbance between LP-AMI/LP-AMI-P equipment and other users of the 2 483,5 MHz to 2 500 MHz frequency range.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.
- Clause 5.3 specifies the methods of measurement for the parameters specified in clause 4, related to transmitter, receiver, and spectrum access.
- Annex A (normative) provides an overview of the relationship between the present document and the essential requirements of the RE-D [i.1].
- Annex B (normative) gives the specifications concerning radiated measurements.
- Annex C (informative) provides the bibliography.

1 Scope

The present document covers, for Low Power Active Medical Implants (LP-AMI) using the band bands 2 483,5 MHz to 2 500 MHz, and associated Peripherals (LP-AMI-P) used in an Active Medical Implant Communications System (AMICS), the required characteristics considered necessary to efficiently use the available spectrum and serve the interests of patients with implanted devices. The specifications contained in the present document were developed to ensure that the health and safety of the patients that are using this equipment under the direction of medical practitioners is protected. Of particular importance is the inclusion of spectrum monitoring and access requirements designed to significantly reduce any interference potential between AMICS operating in the band or between AMICS and other primary or secondary users of the band. An AIMD is regulated under the AIMD Directive 90/385/EEC [i.5] radio parts contained therein (referred to herein as LP-AMI and LP-AMI-P for associated peripheral devices) are regulated under the Directive 2014/53/EU [i.1].

The frequency usage conditions for the bands 2 483,5 MHz to 2 500 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to Commission Implementing Decision 2013/752/EU [i.13] with the following usage restrictions:

- "This set of usage conditions is only available to active implantable medical devices. Peripheral master units are for indoor use only."

The present document contains the technical characteristics for LP-AMI and associated peripherals LP-AMI-P radio equipment which is also addressed by CEPT/ERC/REC 70-03 [i.3] annex 12 sub-band e) 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.

The present document applies to LP-AMI and LP-AMI_P operating in the band 2 483,5 MHz to 2 500 MHz:

- for telecommand and telemetry between LP-AMI and LP-AMI-P;
- for telecommand and telemetry between LP-AMI to another LP-AMI;
- with or without an integral antenna; and/or
- with an antenna connection provided only for the purpose of connecting a dedicated antenna.

The present document contains required characteristics considered necessary for the radio devices used in AMICS 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 AMICS operating in the band or between an AMICS and the primary users of the band.

The present document is a specific product standard applicable to low power transmitters that are part of a system used in the AMICS operating in spectrum within the frequency band 2 483,5 MHz to 2 500 MHz.

The present document contains requirements to demonstrate that Low Power Active Medical Implants (LP-AMI) "*…shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*" (article 3.2 of the Directive 2014/53/EU) [i.1]. The present document does not necessarily include all the requirements which may be required by a user, nor does it necessarily represent the optimum performance achievable.