ICS 33.100.10 SLOVENSKÁ TECHNICKÁ NORMA Február 2017

STN	**Aktívne zdravotnícke implantáty s ultranízkym výkonom (ULP-AMI) a súvisiace periférne zariadenia (ULP-AMI-P) pracujúce vo frekvenčnom rozsahu od 402 MHz do 405 MHz. Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice 2014/53/EÚ.**	**STN EN 301 839 V2.1.1** 87 1839

Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 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. 01/17

Obsahuje: EN 301 839 V2.1.1:2016

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Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2017
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ETSI EN 301 839 V2.1.1 (2016-04)

Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; 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.9] 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:	25 April 2016
Date of latest announcement of this EN (doa):	31 July 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 January 2017
Date of withdrawal of any conflicting National Standard (dow):	31 January 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

ULP-AMI/ULP-AMI-P equipment in the MICS service is an evolving technology, available worldwide in the medical field, that provides 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 MICS service consists of active medical implants that communicate to other active medical implants and/or to ULP-AMI-P as e.g. external programmer/control transmitters.

The present document includes methods of measurement for Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-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.

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.

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 5.3.7 specifies the required measurement methods. In particular clause 5.3.7.1 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 [i.2].

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 the following radio equipment types:

- Ultra Low Power Active Medical Implants (ULP-AMI).
- Ultra Low Power Active Medical Implant Peripherals (ULP-AMI-P).

These radio equipment types are capable of operating in all or any part of the frequency bands in table 1.

Table 1: Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating frequency bands

	Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating frequency bands
Transmit Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz
Receive Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz

The present document contains the technical characteristics for ULP-AMI and ULP-AMI-P radio equipment which is also addressed by ERC/DEC (01)17 [i.1].

It applies to ULP-AMI devices and accessories ULP-AMP-P operating in the frequency band 402 MHz to 405 MHz:

- for telecommand and telemetry to/from an AIMD in a patient's body to an ULP-AMI-P; or
- for telecommand and telemetry to/from an AIMD to another AIMD within the human body.

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) used in a Medical Implant Communications Service (MICS) "… *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.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 http://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): "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] ECC 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 (RE-D).

[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.

NOTE: See http://niremf.ifac.cnr.it/docs/HANDBOOK/home.htm.

[i.6] CEPT/ERC/REC 74-01: "Unwanted Emissions in the Spurious Domain".

[i.7] 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.8] "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.9] 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.

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