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STN	**Zariadenia s krátkym dosahom (SRD) Aktívne zdravotnícke membránové implantáty s ultranízkym výkonom (ULP-AMI-M) a periférne zariadenia (ULP-AMI-M-P) pracujúce vo frekvenčnom rozsahu od 30 MHz do 37,5 MHz Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice 2014/53/EÚ**	**STN EN 302 510 V2.1.1** 87 2510

Short Range Devices (SRD); Ultra Low Power Active Medical Membrane Implants (ULP-AMI-M) and Peripherals (ULP-AMI-M-P) operating in the frequency range 30 MHz to 37,5 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. 01/18

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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.7] 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.

National transposition dates	
Date of adoption of this EN:	27 December 2016
Date of latest announcement of this EN (doa):	31 March 2017
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 September 2017
Date of withdrawal of any conflicting National Standard (dow):	30 September 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).

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Introduction

Membrane Implants and associated peripheral equipment are a new technology in the medical field that provides, on a continuing non-invasive basis after the implant is inserted, patient related real time intravenous blood pressure information to the attending physician. This information is used for purposes of diagnosing and treating certain heart related disorders thereby reducing significantly the hospital readmission rate.

The present document is a specific product standard applicable to Ultra Low Power Active Medical Membrane Implants and Peripherals operating in the frequency range 30 MHz to 37,5 MHz.

The frequency usage conditions for the band 30 MHz to 37,5 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.10].

The present document 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 [i.1].
- 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-Active Medical Membrane Implants and Membrane Implant Peripherals as described in Directive 90/385/EEC [i.4], covering all active medical implants, that operate in a Medical Implant Communications System in the frequency band 30 MHz to 37,5 MHz.

Table 1: Ultra Low Power Active Medical Membrane Implants and Peripherals operating in the frequency band 30 MHz to 37,5 MHz

	Ultra Low Power Active Medical Membrane Implants and Peripherals service frequency bands
Transmitters - Ultra Low Power Active Medical Membrane Implants and peripherals	30 MHz to 37,5 MHz
Receivers - Ultra Low Power Active Medical Membrane Implants and peripherals	30 MHz to 37,5 MHz

The present document contains the technical requirements for characteristics of ULP-AMI-M and ULP-AMI-M-P radio equipment which are aligned with annex 12 Sub-band (d) of CEPT/ERC Recommendation 70-03 [i.6].

The frequency usage conditions for the band 30 MHz to 37,5 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.10] with the following usage restrictions:

- "*This set of usage conditions is only available to ultra-low power medical membrane implants for blood pressure measurements within the definition of active implantable medical devices in Directive 90/385/EEC.*"

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Membrane Implants and peripherals used in a medical membrane implant communications system "*… 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]). 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): "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] 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.2] ETSI TR 100 028 (V1.3.1): "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[i.3] Void.

[i.4] 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.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 Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.7] 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.8] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.9] "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.10] 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.

[i.11] CEPT/ERC Recommendation 74-01: "Unwanted emissions in the spurious domain".