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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

Reference

REN/ERM-TG30-308

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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.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.

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

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".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and definitions apply:

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

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

artificial antenna: reduced-radiating dummy load equal to the nominal impedance specified by the applicant

blocking: measure of the capability of the receiver to receive a wanted modulated signal without exceeding a given degradation due to the presence of an unwanted input signal at any frequencies other than those of the spurious responses in adjacent channels or bands

NOTE: See clause 4.2.2.1.

conducted measurements: measurements which are made using a direct connection to the equipment under test

custom antenna: antenna built according to manufacturer's antenna design rules

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

duty cycle: ratio, expressed as a percentage, of the total transmitter on time to an one hour period under repeated normal operation during the time measurement interval

NOTE 1: Whether the duty cycle is fixed or random depends on how the device is triggered.

NOTE 2: See clause 4.2.1.4.

integral antenna: permanent fixed antenna, which may be built-in, that is designed as an indispensable part of the equipment

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

out of band emissions: emissions resulting from the modulation process that are outside the emission bandwidth, but excluding unwanted emission in the spurious domain

NOTE: See clause 4.2.1.2.

programmer/controller: equipment used by a physician to communicate with an implanted device

radiated E-field: E-field in the direction of maximum field strength under the specified conditions of measurement

NOTE: See clause 4.2.1.1.

radiated measurements: measurements which involve the absolute measurement of a radiated field

spurious radiations from receivers: emissions radiated from the antenna, the chassis and case of the receiver

NOTE: It is specified as the radiated power of a discrete signal. Included in this definition are modulation products that are outside the 20 dB down point on either side of the fundamental emission. See clause 4.2.2.2.

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

Ultra Low Power Active Medical Implant (ULP-AMI): radio part of an AIMD

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P): radio part of equipment outside the human body that communicates with an ULP-AMI

ultra low power active medical implant membrane (ULP-AMI-M): active medical implant device with resonant transmission capability that operates in a ULP-AMI band and is placed inside the human body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

ultra low power active medical implant membrane peripheral(ULP-AMI-M-P): transmitter, operating outside of a human body in a ULP-AMI frequency band that transmits energy to a membrane implant with a receiver that receives information from a membrane implant for the purpose of determining pressure within the human body

unwanted emissions in the spurious domain: emissions on a frequency or frequencies which are outside the out of band domain and the level of which may be reduced without affecting the corresponding transmission of information

NOTE: Emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation. See clause 4.2.1.3.

3.2 Symbols

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

E	Electrical field strength
f	frequency
P	Power
R	Distance
t	time

3.3 Abbreviations

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

AIMD	Active Implantable Medical Device
AMD	Active Medical Device
e.r.p.	Effective Radiated Power
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
ULP-AMI-M	Ultra Low Power Active Medical Implant Membrane
ULP-AMI-M-P	Ultra Low Power Active Medical Implant Membrane Peripheral

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.

4.2 Conformance requirements

4.2.1 Transmitter requirements

4.2.1.1 Effective Radiated Power

4.2.1.1.1 Definition

The effective radiated power is the 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.