SLOVENSKI STANDARD
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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Radijska oprema v frekvenčnem območju od 30 MHz do 37,5 MHz za aktivne membranske medicinske vsadke ultra majhnih moči in pribor - 1. del: Tehnične karakteristike in preskusne metode

Electromagnetic compatibility and Radio spectrum Matters (ERM) - Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories - Part 1: Technical characteristics and test methods

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Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 1: Technical characteristics and test methods

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Foreword

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

For non-EU countries the present document may be used for regulatory (Type Approval) purposes.

The present document is part 1 of a multi-part deliverable covering inductively coupled Ultra Low Power Active Medical Implant Membrane (ULP-AMI-M) devices in the frequency range 30 MHz to 37,5 MHz, as identified below:

Part 1: "Technical characteristics and test methods";

Part 2: "Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

National transposition dates	
Date of adoption of this EN:	15 June 2007
Date of latest announcement of this EN (doa):	30 September 2007
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1 Scope

The present document applies to Ultra Low Power Active Medical membrane implant transmitters and receiver/activators operating in the range from 30 MHz to 37,5 MHz and any associated radio apparatus including patient related telecommunication devices using digital modulation techniques.

An active implantable medical device (AIMD) is regulated under the AIMD Directive 90/385/EEC [4]: radio parts contained therein (referred to herein as ULP-AMI and ULP-AMI-P for peripheral devices) are regulated under the R&TTE Directive 1999/5/EC [5].

The present document applies to ULP-AMI equipment conforming to the following:

- implantable membrane technology;
- external equipment with an antenna connection and/or with an integral antenna;
- for use as telecommunications and/or telecommand transmission to/from active medical membrane implant.

The present document covers physician operated programmer/controller transmitters (typically fixed stations), patient operated external transmitters (fixed or mobile stations) and implanted radio transmitting devices (portable stations).

All types of membrane implant technology for radio devices are covered by the present document, provided the requirements of clause 7 are met.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication and/or edition number or version number) or non-specific.
- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version 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.

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

[2] "Radiofrequency Radiation Dosimetry Handbook" (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

[3] ETSI TR 100 028 (V1.3.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[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 (AMD Directive).

[5] Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (R&TTE Directive).

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: a 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 8.1.1.

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

custom antenna: antenna built according to manufacturers 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 of the total on time of the "message" to the total off time in any one hour period under repeated normal operation during the time measurement interval

NOTE: Whether the duty cycle is fixed or random depends on how the device is triggered. See clause 7.5.1.

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

medical implant membrane device (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

medical implant membrane programmer/control transmitter: transmitter, operating outside of a human body in a ULP-AMI frequency band that transmits to and receives information from a membrane implant for the purpose of determining pressure within the human body

out of band emissions: emissions resulting from the modulation process that are outside the declared band

NOTE: See clause 7.3.1.

programmer/controller: ULP-AMI-P 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 7.2.2.

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 8.2.1.

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) device: radio part of equipment outside the human body that communicates with an ULP-AMI

unwanted emissions in the spurious domain: emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation

NOTE: See clause 7.4.1.

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
EMC	ElectroMagnetic Compatibility
ERP	Effective Radiated Power
EUT	Equipment Under Test
OATS	Open Area Test Site
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-M	Ultra Low Power Active Medical Implant Membrane transmitter
VSWR	Voltage Standing Wave Ratio

4 Technical requirements and specifications

4.1 General requirements

4.1.1 Receiver classification

The product family of ULP-AMI radio devices is divided into three receiver classes, see table 1, each having its own set of minimum performance criteria. This classification is based upon the impact on persons in case the equipment does not operate above the specified minimum performance level. Applicable equipment classification shall be specified by the manufacturer.

Table 1

Receiver class	Relevant receiver clauses	Risk assessment of receiver performance
1	8.1	Highly reliable ULP-AMI communication media; e.g. serving human life inherent systems (may result in a physical risk to a person)
2	8.1	Medium reliable ULP-AMI communication media e.g. when a failure to operate causes inconvenience to persons, which cannot simply be overcome by other means
3	8.1.1	Standard reliable ULP-AMI communication media e.g. when a failure to operate causes inconvenience to persons, which can simply be overcome by other means (e.g. manual)
NOTE: In particular where an ULP-AMI-M which may have an inherent safety of human life implication, manufacturers and users should pay particular attention to the potential for interference from other systems operating in the same or adjacent bands.		

4.1.2 General performance criteria

For the purpose of the receiver performance tests, the receiver shall produce an appropriate output under normal conditions. Where the indicated performance cannot be achieved or if it is defined differently, the manufacturer shall declare and publish the performance criteria used to determine the performance of the receiver.

4.2 Presentation of equipment for testing purposes

The applicant shall declare the operating frequency, the range of operating conditions and power requirements in consultation with the laboratory, as applicable, to establish the appropriate test conditions.

Additionally, technical documentation and operating manuals, sufficient to make the test, shall be supplied.

A test fixture for equipment with an integral antenna may be supplied by the applicant (see clauses 6.3). For equipment supplied with an external antenna the applicant shall provide the antenna and a suitable test fixture as needed. In general, compliance must be shown by performing radiated electric field strength measurements.

4.2.1 Choice of model for testing

The applicant shall provide one or more samples of the equipment, as appropriate for testing.

Stand alone equipment shall be offered by the applicant complete with any ancillary equipment needed for testing.

If an equipment has several optional features, considered not to affect the RF parameters then the tests need only to be performed on the equipment configured with that combination of features considered to be the most complex, as proposed by the applicant and agreed by the test laboratory.

In the case of integral or dedicated antenna equipment, if the equipment does not have an internal permanent 50 Ω connector then it is permissible to supply a second sample of the equipment with a temporary antenna connector fitted to facilitate testing, see clause 4.2.2.

4.2.2 Testing of equipment that does not have an external RF connector (integral antenna equipment)

This type of equipment will normally be tested by performing radiated tests at 3 meters. For devices with very low radiated field levels, measurements may be made at closer distance and the levels extrapolated to 3 meters using an inverse linear extrapolation rate.