SLOVENSKI STANDARD
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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) ï Radijska oprema v frekvenļ nem obmoļ ju od 9 kHz do 315 kHz za aktivne medicinske vsadke ultra majhnih moļ i (ULP-AMI) in pribor ï 1. del: Tehniļ ne karakteristike in preskusne metode

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP -AMI) 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 Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories, 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:	12 March 2004
Date of latest announcement of this EN (doa):	30 June 2004
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 December 2004
Date of withdrawal of any conflicting National Standard (dow):	31 December 2004

1 Scope

The present document applies to Ultra Low Power Active Medical Implant (ULP-AMI) transmitters and receivers operating in the range from 9 kHz to 315 kHz and any associated radio apparatus transmitting in the frequency range of 9 kHz to 315 kHz including external programmers and patient related telecommunication devices using digital modulation techniques such as, but not limited to, FSK or pulse position modulation. Analogue voice modulation is not within the scope of the present document.

The present document contains the technical characteristics and test methods for radio equipment and is referenced in CEPT/ERC Recommendation 70-03 [2], annex 12 band(b).

The present document does not necessarily include all the characteristics which may be required by a user, nor does it necessarily represent the optimum performance achievable. It is a product standard which may be completely or partially superseded by specific standards covering specific applications.

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

- inductive loop systems;
- with an antenna connection and/or with an integral antenna;
- for use as telecommunications and telecommand transmission to/from active medical implants.

ULP-AMI equipment has an inherent safety of human life implication, manufacturers and users are cautioned to pay particular attention to the potential for interference from other systems operating in the same or adjacent bands.

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

All types of digital modulation for radio devices are covered by the present document.

The radio equipment, covered by the classification SRD is divided into several power classes based on maximum radiated field strength or output power (see table 1). The power class designation is based on CEPT/ERC Recommendation 70-03 [2] and ERC Decisions.

Table 1: Maximum radiated H-field

Power Class	Radiated H-field or power level
1	7 dBµA/m at 10 m
2	42 dBµA/m at 10 m
3	72 dBµA/m at 10 m (at 9 kHz to 30 kHz, descending 3 dB/octave from 30 kHz to 135 kHz)
4	37,7 dBµA/m at 10 m (at 135 kHz, descending 3 dB/octave from 135 kHz to 1 MHz)
	29 dBµA/m at 10 m (at 1,0 MHz descending 9 dB/octave from 1 MHz to 4,642 MHz)
5	9 dBµA/m at 10 m (4,642 MHz to 30 MHz)
	30 dBµA/m at 10 m (9 kHz to 315 kHz)

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.

[1] 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).

[2] CEPT/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

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

[4] ETSI ETR 028: "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics".

[5] Air Force Technical Report AL/OE-TR-1996-0037: "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

active medical implant: diagnostic or therapeutic device designed to be implanted in a human body containing a power source and capable of generating radio frequency energy within the 9 kHz to 315 kHz frequency band for the purpose of providing a digital communications link

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

assigned frequency: frequency within the applicable band on which the device is authorized to operate

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 that is designed as an indispensable part of the equipment

fixed station: equipment intended for use in a fixed location

H-field test antenna: electrically screened loop or equivalent antenna, with which the magnetic component of the field can be measured

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

magnetic dipole moment: product of (Number of coil turns) × (coil area) × (coil current)

NOTE: Air coils only.

medical implant device: apparatus that includes a transmitter with an integral receiver that operates in the ULP-AMI band that is placed inside the human body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

medical implant programmer/control transmitter: a transmitter, operating outside of a human body in the ULP-AMI frequency band that transfers information to/from the implant after a communications link is initiated

mobile station: equipment external to the body, normally used by a patient, to provide telecommand or telemetry communication functions to a medical implant device placed within the body

patient activator: equipment intended to be used by a patient to communicate with an implanted device

portable station: equipment intended to be carried, attached or implanted in a human body that is operated at a separation distance less than 20 cm from or internal to a human body

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

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

telecommand: use of radio communication for the transmission of signals to initiate, modify or terminate functions of equipment at a distance

telecommunications: use of radio communications for the transmission of data between various ULP-AMI devices

telemetry: use of radio communication for indicating or recording data at a distance

Ultra Low Power Active Medical Implant (ULP-AMI): active medical implant transmitter or associated medical implant programmer/control transmitter that is designed to radiate RF energy in accordance with the provisions of annex 12, band (b), to CEPT/ERC Recommendation 70-03 [2] and EN 302 195-1

3.2 Symbols

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

E	Electrical field strength
Eo	Reference electrical field strength (see annex A)
f	frequency
H	Magnetic field strength
Ho	Reference magnetic field strength (see annex A)
m	magnetic dipole moment
P	Power
R	Distance
Ro	Reference distance (see annex A)
t	time

3.3 Abbreviations

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

EMC	ElectroMagnetic Compatibility
RF	Radio Frequency
R&TTE	Radio and Telecommunications Terminal Equipment
SRD	Short Range Device
ULP-AMI	Ultra Low Power Active Medical Implant

4 Technical requirements specifications

4.1 General requirements

4.1.1 Receiver classification

The product family of ULP-AMI radio devices is divided into three Equipment Classes, see table 2, 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 2

Receiver class	Relevant receiver clauses	Risk assessment of receiver performance
1	8.1 and 8.2	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 and 8.2	Medium reliable ULP-AMI communication media e.g. causing Inconvenience to persons, which cannot simply be overcome by other means
3	8.2	Standard reliable ULP-AMI communication media e.g. Inconvenience to persons, which can simply be overcome by other means (e.g. manual)
NOTE: In particular where an ULP-AMI 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

The receiver performance shall be in conformity with the specifications declared by the manufacturer. Where the intended performance cannot be achieved under testing, 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

Each equipment submitted for testing where type approval is still in force shall fulfil the requirements of the present document on all frequencies over which it is intended to operate.

The applicant shall declare the operating frequency, the range of operating conditions and power requirements in consultation with the accredited 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 clause 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 magnetic field strength measurements.

If an equipment is designed to operate with different radiated field strengths or power level, measurement of each transmitter parameter shall be performed, according to the present document, on samples of equipment defined in clause 4.2.1.

To simplify and harmonize the testing procedures between different testing laboratories, measurements shall be performed, according to the present document, on samples defined in clause 4.2.1.