SLOVENSKI STANDARD
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Elektromagnetna združljivost (EMC) in zadeve v zvezi z radijskim spektrom (ERM) - Radijska oprema v frekvenčnem območju od 402 MHz do 405 MHz za aktivne medicinske implantate in pribor ultra majhnih moči - 1. del: Tehnične karakteristike, vključno z zahtevami elektromagnetne združljivosti in s preskuševalnimi metodami

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods

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Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, 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).

The present document is part 1 of a multi-part deliverable covering Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories, as identified below:

Part 1: "Technical characteristics, including electromagnetic compatibility requirements, 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:	7 June 2002
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Introduction

The present document is drafted on the assumption that type test measurements, performed in an accredited test laboratory will be accepted by the various National Regulatory authorities in order to grant type approval, provided the National Regulatory requirements are met. This is in compliance with CEPT/ERC/REC 01-06E [2].

Included are methods of measurement for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories, 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 and abbreviations used.

Clause 4 provides a guide to essential requirements, the number of samples required in order that type tests may be carried out and any markings on the equipment that the applicant has to provide.

Clauses 5 and 6 provide general test conditions to be used.

Clause 7 gives the maximum measurement uncertainty values.

Clauses 8, 9, 10 and 11 specify the spectrum utilization and safety parameters that are required to be determined for the protection of the public. They contain the maximum limits and monitoring system performance specifications that have been chosen to minimize harmful disturbance to other equipment or services, reduce the potential for disturbance to this equipment from ambient sources, and protect the public. The clauses provide details on how the equipment should be tested and the conditions that should be applied.

Clause 12 specifies the electromagnetic compatibility testing and measurement requirements for insuring the health and safety of the users of active medical implants and accessories are protected.

Annex A provides normative specifications concerning radiated measurements.

Annex B provides normative specifications for test equipment.

1 Scope

The present document covers, for Ultra Low Power-Active Medical Implants (ULP-AMI) and accessories used in a Medical Implant Communications Service (MICS), the required characteristics considered necessary to efficiently use the available spectrum and protect the public. ULP-AMI equipment and accessories in the MICS service is a unique new technology, available world wide in the medical field, that will provide high speed communications capability between individuals with implanted devices and medical practitioners engaged in utilizing these implants for the purposes of diagnosing and delivering therapy to individuals with various illnesses. The specifications contained in the present document were developed to insure that the health and safety of the patients that are using this equipment under the direction of medical practitioners is protected. Of particular importance is the inclusion of spectrum monitoring and access requirements (listen before talk protocol) designed to significantly reduce any interference potential between MICS systems operating in the band or between a MICS system and the primary users of the band. Equipment in the MICS service consists of active medical implants that communicate only to other active medical implants or to external programmer/control transmitters.

The present document is a specific product standard applicable to active medical implants operating in the frequency band, 402 MHz to 405 MHz, and other radio devices that are considered to be accessories to active medical implants as described in Directive 90/385/EEC [6]. It is intended that the present document applies to operation in the band 402 MHz to 405 MHz only and that devices that can also operate in spectrum outside this band also meet any applicable requirements for operation in such bands.

The present document contains the technical characteristics for ULP-AMI radio equipment and is referencing CEPT/ERC/REC 70-03 [3] and annex 12 to that document. It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

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

- for telecommand and telemetry to/from an implant in a patient's body to an external programmer/controller unit; or
- for telecommand and telemetry to/from an implant to another implant within the human body;
- with or without an integral antenna; and/or

- with an antenna connection provided only for the purpose of connecting an external dedicated antenna.

Compliance with the radiated emissions provisions of the present document is determined using a substitution technique. However, if calibrated half wave dipole antennas are used to measure the radiated field strength of the emissions from the EUT, it is permissible to calculate the erp levels of those emissions to show compliance.

NOTE: If this technique is used, the ground reflected component of the measured field strength needs to be accounted for. For purposes of computing erp levels, the contribution to the measured level that is due to the ground reflected ray is considered to be 5 dB if measurements are performed on an open area test site or equivalent.

For non-Harmonized parameters, national regulatory conditions can apply regarding the type of modulation, equipment marking and the inclusion of an automatic transmitter shut-off facility as a condition of the issue of an individual or general licence, or, as a condition of use under licence exemption. The extreme temperature and voltage ranges are fixed and are given in clauses 5.4.1 and 5.4.2 respectively.

The present document covers requirements for radiated emissions above 25 MHz.

Additional standards or specifications may be required for equipment such as that intended for connection to the Public Switched Telephone Network (PSTN).

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.

[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/REC 01-06: "Procedure for mutual recognition of type testing and type approval for radio equipment".

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

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

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

[6] 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).

[7] EN 60601-1-2: "Medical electrical equipment; Part 1: General requirements for safety; Part 2: Collateral standard: Electromagnetic compatibility - Requirements and tests".

[8] ITU-R Recommendation SA.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".

[9] CISPR 16-1: "Specification for radio disturbance and immunity measuring apparatus and methods; Part 1: Radio disturbance and immunity measuring apparatus".

[10] ICNIRP: "Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz), International Commission on Non-Ionizing Radiation Protection, Health Physics Vol. 74, No 4, pp 494-522, 1998".

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

[12] ANSI C63.17 (1998): "Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (UPCS) Devices".

[13] EN 45502-1: "Active implantable medical devices; Part 1: General requirements for safety, marking and information to be provided by the manufacturer".

[14] Council Recommendation 1999/519/EC on limitation of exposure of the general public to electromagnetic fields 0 Hz-300 GHz.

[15] ETSI ETS 300 683: "Radio Equipment and Systems (RES); ElectroMagnetic Compatibility (EMC) standard for Short Range Devices (SRD) operating on frequencies between 9 kHz and 25 GHz".

[16] ETSI EN 301 489-3: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

access protocol: specification for measuring natural and man-made ambient background levels for the purpose of providing a technique for spectrum access that reduces the potential for harmful disturbance to/from other users of the spectrum

active medical implant: diagnostic or therapeutic device designed to be implanted in a human body containing a power source and a transceiver using the 402 MHz to 405 MHz frequency band for the purpose of providing a two-way digital communications link

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

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

channel bandwidth: 3 MHz divided by the system emission bandwidth plus any specified guard band at each channel edge

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

dedicated antenna: permanently attached or removable antenna supplied and type tested with the radio equipment, 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

NOTE: Compliance is determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1 % of the emission bandwidth of the device under test.

fixed station: equipment intended for use in a fixed location

full tests: all tests specified in EN 301 839-1

integral antenna: permanent fixed antenna designed as an indispensable part of the equipment

Least Interfered Channel (LIC): channel, among the available channels that has the lowest potential for causing disturbance to or receiving disturbance from other users of the band, determined by measuring the level from both natural and man-made signal sources in available channels and selecting the channel with the lowest measured ambient power level or the channel with the lowest measured ambient power level that exceeds the calculated maximum permissible threshold power level

listen before talk: performance requirement, usually in the form of a protocol, that requires a communications system to determine if the channel it intends to communicate in is occupied by another user and select from the available spectrum a channel for communication that reduces, to the extent possible, the potential for interference to/from another user of the spectrum

Medical Implant Communications System (MICS): system specifically for the purpose of providing two way non-voice digital communications between an external programmer/control transceiver and an active medical implant transceiver or between active medical implant transceivers placed in a human body

Medical Implant Communications System (MICS) channel: any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MICS communications session

NOTE 1: All medical implant communications systems must be designed to access a minimum of nine channels evenly distributed across the band.

NOTE 2: Annex 12 to CEPT/ERC/Recommendation 70-03 [3] does not specify a channelling plan for ULP-AMI devices. It permits aggregation of 25 kHz segments up to a maximum of 300 kHz for each channel bandwidth.

Medical Implant Communications System (MICS) session: collection of transmissions that may or may not be continuous, between co-operating medical implant devices and accessories, including programmer/controllers, transferring patient related information in communications service

Medical Implant Communications System (MICS) transmitter: transmitter with an integral receiver authorized to operate in the ULP-AMI band from 402 MHz to 405 MHz

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 event: occurrence or the lack of an occurrence recognized by a medical implant device or duly authorized health care professional that requires the immediate transmission of data from a medical implant transmitter in order to protect the safety of the person in whom the medical implant transmitter has been placed

NOTE: It is not permitted that this is the only mechanism a medical implant transmitter can use to access spectrum. All medical implant transmitters must have the ability and typically use this ability to transfer information to/from a medical implant programmer/control transmitter on a frequency that has been selected by the programmer/control transmitter using the LIC spectrum access protocol specified in the present document.

medical implant programmer/control transmitter: transmitter, operating outside of a human body in the ULP-AMI frequency band, that is designed to monitor the channel or channels the MICS system devices intend to occupy that selects, a communications channel for a link to a medical implant transmitter based on the use of the LBT access protocol, and transfers information to/from the implant after initiating the communications link

medical implant transmitter: a transmitter with an integral receiver operating in the ULP-AMI frequency band, whose frequency of operation is determined by an associated transmitter that uses the LIC access protocol specified in the present document, that is designed to be placed within a human body for the purpose of providing two-way digital communications

NOTE: A medical implant transmitter, designed and capable of operation in accordance with the above definition, may transmit without using the LIC spectrum access protocol if a medical implant event occurs as defined above.

mobile station: equipment normally fixed in a vehicle and intended to be used at a distance more than 20 cm from a human body

monitoring system: circuitry in a medical implant transmitter or an associated programmer/control transmitter that assures conformity with the spectrum access protocol requirements

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

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

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

threshold power level: ambient signal power level above which the monitoring system shall select spectrum for use in a MICS communication session according to the next available channel with the lowest level of ambient signal power or least interfered channel (LIC)

NOTE: The maximum permitted threshold power level is calculated using the equation $Th_p = 10\log B(Hz) - 150\ (dBm/Hz) + G\ (dBi)$.

Ultra Low Power Active Medical Implant (ULP-AMI): active medical implant transmitter or medical implant programmer/control transmitter that is designed to radiate RF energy in accordance with the provisions of annex 12 to CEPT/ERC/Recommendation 70-03 and EN 301 839-1

wideband: equipment used in the ULP-AMI frequency band with an emission bandwidth ≥ 50 kHz and ≤ 300 kHz

3.2 Symbols

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

dB	decibel
E	electrical field strength
Eo	reference electrical field strength (see annex A)
f	frequency
FT	Full Test (see clause 3.1)
NaCl	sodium chloride
P	power
R	distance
Ro	Reference distance (see annex A)
Th_p	maximum threshold power level (see clause 10)
t	time
λ	wavelength

3.3 Abbreviations

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

CW	Continuous Wave
EUT	Equipment Under Test
LIC	Least Interfered Channel (see definitions)
MICS	Medical Implant Communications System
PSTN	Public Switched Telephone Network
RF	Radio Frequency
SRD	Short Range Device
ULP-AMI	Ultra Low Power Active Medical Implant
VSWR	Voltage Standing Wave Ratio

4 Overview of technical requirement specifications

4.1 Essential requirements

4.1.1 Transmitter requirements

All transmitter requirements that are considered as essential are specified in EN 301 839-2. See clause 8 for requirements and measurement procedures.

4.1.2 Receiver requirements

Receiver spurious emissions requirements are considered essential as specified in EN 301 839-2. See clause 9 for requirements and measurement procedures.

4.2 Presentation of equipment for testing purposes

Each equipment submitted for testing shall fulfil the requirements of the present document on all frequencies over which it is intended to operate. Compliance with this requirement should be shown by testing each unit on a frequency near 403,5 MHz.

If equipment is designed to operate with different carrier powers, measurement of each transmitter parameter shall be performed at the highest power level at which the transmitter is intended to operate. Additionally, the spurious emissions shall be measured at each lower power level setting or at the low, middle, and high power settings for multilevel power control systems.

The applicant shall complete the appropriate application form when submitting the equipment for testing. In addition, the applicant shall declare the range of operating conditions and power requirements, as applicable; to establish the appropriate test conditions.

Additionally, technical documentation and operating manuals, sufficient to make the test, shall be supplied for all programmer/control and implant devices.

A human torso simulator and tissue substitute material for active medical implant transmitters shall be supplied (see clause 6.5) if requested by the test facility.

To simplify and harmonize the type testing procedures between the different testing laboratories, measurements shall be performed, according to the present document, on samples of equipment defined in clauses 4.2.1 to 4.2.3.3.

4.2.1 Choice of model for testing

The applicant shall provide one or more samples of each model or type of transmitter (medical implant and/or programmer/control transmitters), as appropriate for testing. Any ancillary equipment needed for testing shall be provided as requested by the testing laboratory.

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 or most likely to affect the RF parameters, as proposed by the applicant and agreed to by the test laboratory.

4.2.2 Testing of equipment with alternative power levels

If equipment is designed to operate with different carrier powers, measurement of each transmitter parameter shall be performed at the highest power level, according to the present document, on samples of equipment defined in clause 4.2.1. Spurious emissions tests shall be performed at all power levels.

4.2.3 Testing of equipment that does not have an external 50 Ω RF connector (integral antenna equipment)

4.2.3.1 Equipment with an internal permanent or temporary antenna connector

The means to access and/or implement the internal permanent or temporary connector shall be stated by the applicant with the aid of a diagram. The fact that use has been made of the internal antenna connection, or of a temporary connection, to facilitate measurements shall be recorded in the test report.

No connection shall be made to any internal permanent or temporary antenna connector during the performance of radiated emissions measurements, unless such action forms an essential part of the normal intended operation of the equipment, as declared by the applicant.

4.2.3.2 Equipment with a temporary antenna connector

The applicant may submit one set of equipment with the normal antenna connected, to enable the radiated measurements to be made. He shall attend the test laboratory at the conclusion of the radiated measurements, to disconnect the antenna and fit the temporary connector. The testing laboratory staff shall not connect or disconnect any temporary antenna connector.

Alternatively, the applicant may submit two sets of equipment to the test laboratory, one fitted with a temporary antenna connector with the antenna disconnected and the other with the antenna connected. Each equipment shall be used for the appropriate tests. The applicant shall declare that two sets of equipment are identical in all respects.

4.2.3.3 Equipment intended to be implanted in a human body

The applicant shall submit the equipment, a human torso simulator as described in clause 6.5 and annex A, and a sufficient quantity of tissue substitute material to fill the test fixture. The applicant and/or test laboratory shall determine and agree on the arrangement of the equipment antenna and any additional device leads on the implant holding grid within the fixture as prescribed in annex A.