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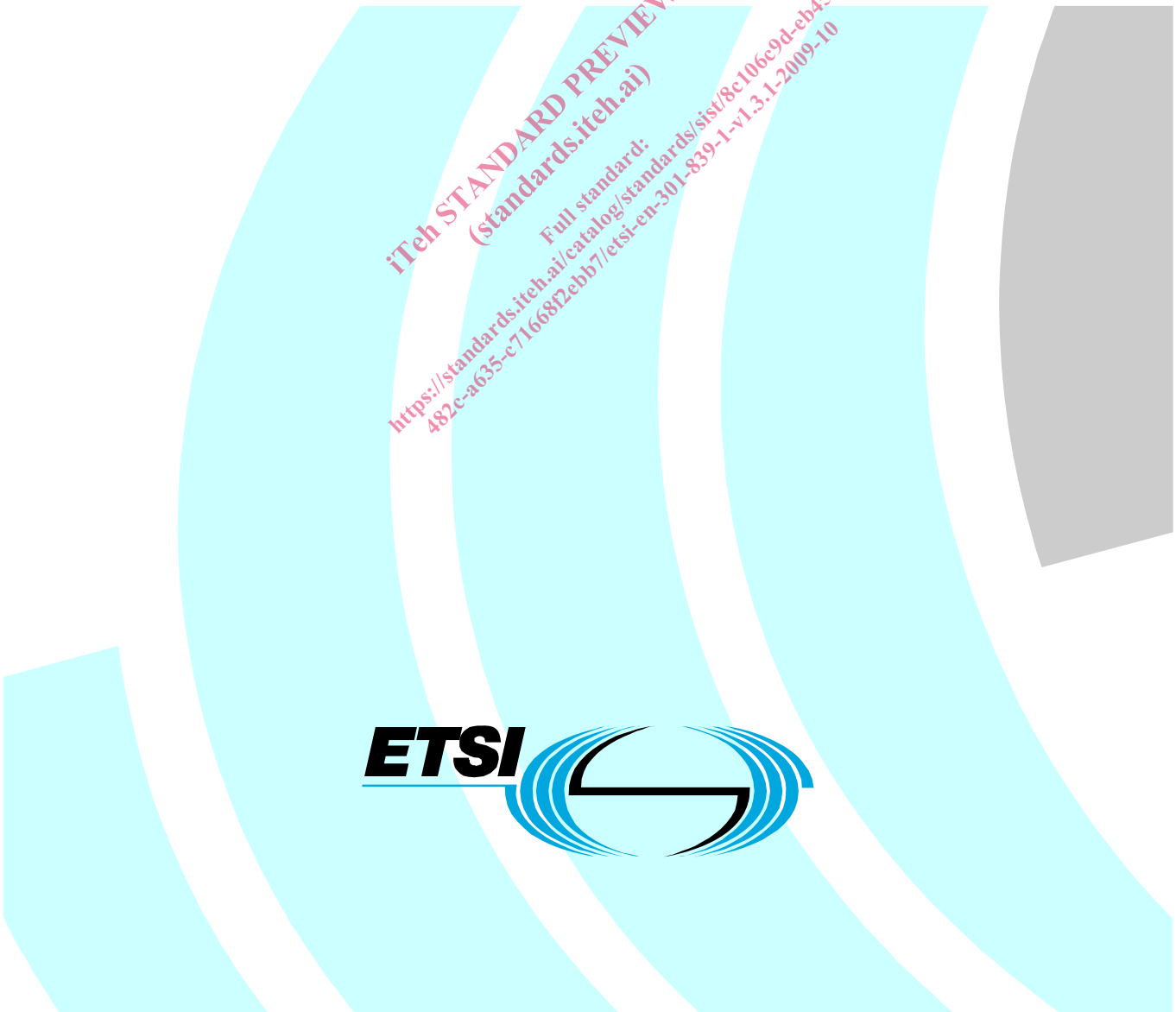
European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods



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Contents

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Foreword

This European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the Vote phase of the ETSI standards Two-step Approval Procedure.

For non EU countries the present document may be used for regulatory purposes.

The present document is part 1 of a multi-part deliverable covering Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 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".

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	6 months after doa
Date of withdrawal of any conflicting National Standard (dow):	6 months after doa

Introduction

ULP-AMI/ULP-AMI-P equipment 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 AIMDs and medical practitioners engaged in utilizing these AIMDs for the purposes of diagnosing and delivering therapy to individuals with various illnesses. Equipment in the MICS service consists of active medical implants that communicate to other active medical implants and/or to ULP-AMI-P as e.g. external programmer/control transmitters.

The present document includes methods of measurement for Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P), 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, symbols and abbreviations used.

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

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

Clause 7 gives the maximum measurement uncertainty values.

Clauses 8, 9 and 10 specify spectrum utilization parameters and the measurement methods that are required for the protection of the spectrum and patient. Clause 10 describes channel access requirements and methods. In particular clause 10.1 describes the monitoring system performance specifications that have been chosen to minimize harmful interference to other equipment or services, reduce the potential for disturbance to this equipment from ambient sources or other medical device users in the band and provide a high degree of link reliability in the interest of the patient.

Annex A (normative) provides specifications concerning radiated measurements.

Annex B (normative) provides specifications for test equipment.

Annex C (informative) provides Strategy for ULP-AMI/ULP-AMI-P in the band 402 MHz to 405 MHz (source ERM_TG30 see URL: http://www.etsi.org).

Annex D (informative) bibliography; provides additional information.

1 Scope

The present document covers, for Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) used in a Medical Implant Communications Service (MICS), the required characteristics considered necessary to efficiently use the available spectrum and serve the interests of implant users. The specifications contained in the present document were developed to ensure 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. Also included in the present document is the capability of Low Duty Cycle/Low Power Access in the 403,5 MHz to 403,8 MHz frequency band.

An AIMD is regulated under the AIMD Directive 90/385/EEC [i.10]: radio parts contained therein (referred to herein as ULP-AMI and ULP-AMI-P for peripheral devices) are regulated under the Directive 1999/5/EC [i.1] (R&TTE Directive).

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 which is also addressed by CEPT/ERC/REC 70-03 [i.2] 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 AIMD in a patient's body to an ULP-AMI-P; or
- for telecommand and telemetry to/from an AIMD to another AIMD 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.

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

2 References

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.
- Non-specific reference may be made only to a complete document or a part thereof and only in the following cases:
  - if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of the referring document;
  - for informative references.

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.

2.1 Normative references

The following referenced documents are indispensable for the application of the present document. For dated references, only the edition cited applies. For non-specific references, the latest edition of the referenced document (including any amendments) applies.

[1] CISPR 16-2-3 (2003): "Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".

[2] ETSI TR 100 028 (all parts) (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

2.2 Informative references

The following referenced documents are not essential to the use of the present document but they assist the user with regard to a particular subject area**.** For non-specific references, the latest version of the referenced document (including any amendments) applies.

[i.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).

[i.2] CEPT/ERC/REC 70-03 (02-2007): "Relating to the use of Short Range Devices (SRD)".

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

[i.4] ITU-R Recommendation RS.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".

[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/REC 74-01: "Unwanted Emissions in the Spurious domain Domain".

[i.7] ERC/DEC(01)17: "ERC Decision of 12 March 2001 on harmonized frequencies, technical characteristics and exemption from individual licensing of short Range Devices used for Ultra Low Power Active Medical Implants operating in the frequency band 402 - 405 MHz".

[i.8] ETSI EN 301 839-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[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] 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).

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 interference to/from other users of the spectrum

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

Adaptive Frequency Agility (AFA): ability to determine an unoccupied sub-band or channel of operation in order to maximize spectrum utilization

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

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

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 maximum transmitter "on" time monitored over one hour, relative to a one hour period

NOTE: See clause 8.6.1.

effective radiated power: power radiated within the emission bandwidth of the EUT in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate

NOTE: See clause 8.3.1.

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: See clause 8.2.1.1 for details on how to determine compliance.

frequency error: difference between the nominal frequency as measured on the devices under test and under normal test conditions and the frequency under extreme conditions

NOTE: See also clause 8.1.1.

frequency stability under low voltage condition: ability of the equipment to remain on the nominal operating frequency when the battery voltage falls below the lower extreme voltage level

NOTE: See also clause 8.5.1.

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

LBT threshold power level: ambient signal power level above which the monitoring system selects 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)

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

Listen Before Talk (LBT): combination of the listen mode followed by the talk mode

listen mode: action taken by an interrogator to detect an unoccupied sub-band or channel

Medical Device (MD): any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means

medical implant communication 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 MICL session

NOTE 1: As stated in CEPT/ERC/REC 70-03 [i.2], annex 12 Band a, it is permitted to aggregate 25 kHz segments up to a maximum of 300 kHz for each channel bandwidth.

NOTE 2: Two types of devices for Medical Implant Communications Systems are covered by the present document:

(i) Frequency agile devices designed to access a minimum of nine channels evenly distributed across the 402 MHz to 405 MHz band.

(ii) Single frequency devices restricted to the 403,5 MHz to 403,8 MHz centre channel.

Medical Implant Communication Link (MICL): collection of transmissions that may or may not be continuous, between ULP-AMIs and ULP-AMI-Ps, including programmer/controllers, transferring patient related information in a communications service

Medical Implant Communications System (MICS): system specifically for the purpose of providing non-voice digital communications between one or several ULP-AMI and one ULP-AMI-P or between ULP-AMI

Medical Implant Communications System (MICS) session: collection of transmissions that may or may not be continuous, between co-operating ULP-AMI and ULP-AMI-P

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.

monitoring system: circuitry in an ULP-AMI and/or ULP-AMI-P that assures conformity with the spectrum access protocol requirements based on Listen before Talk, Adaptive Frequency Agility and selection of the least interfered channel for operation (LIC)

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

spurious domain radiations from the receiver: components at any frequency, generated and radiated by active receiver circuitry and the antenna

NOTE: See clause 9.1.1.

talk mode: transmission of intentional radiation by a transmitter

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

time-critical data: data which if not transferred immediately will result in compromising the health and/or safety of the patient

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

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

unwanted emissions: emissions in the spurious domain and out of band domain

NOTE: See clause 8.4.1.

3.2 Symbols

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

B	bandwidth
dB	decibel
E	electrical field strength
Eo	reference electrical field strength (see annex A)
f	frequency
f_c	channel centre frequency
f_e	frequency under extreme conditions
G	Antenna Gain
NaCl	sodium chloride
P	power
R	distance
Ro	Reference distance (see annex A)
P_{Th}	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:

AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
CW	Continuous Wave
e.r.p.	effective radiated power
EUT	Equipment Under Test
LBT	Listen Before Talk
LDC	Low Duty Cycle
LIC	Least Interfered Channel

NOTE: See definitions.

LP	Low Power
MD	Medical Device
MICL	Medical Implant Communication Link
MICS	Medical Implant Communications System
RF	Radio Frequency
r.m.s.	root mean square
SRD	Short Range Device
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral
VSWR	Voltage Standing Wave Ratio

4 Technical requirements and specifications

4.1 General requirements

4.1.1 Transmitter requirements

See clause 8 for transmitter requirements.

4.1.2 Receiver requirements

See clause 9.

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.

The provider shall complete the appropriate application form when submitting the equipment for testing. In addition, the provider 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 ULP-AMI-P and ULP-AMI.

A human torso simulator and tissue substitute material for testing ULP-AMI shall be used (see clause 6.5).

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 provider shall supply one or more samples of each model or type of transmitter (ULP-AMI and/or ULP-AMI-P), 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 provider and agreed to by the test laboratory.

4.2.2 Testing of equipment with alternative power levels

Equipment designed to operate with different carrier powers shall have each transmitter parameter tested on samples of equipment defined in clause 4.2.1. See clause 8 for details on testing. Spurious domain emissions tests shall be performed in accordance with requirements in clause 8.4.1.1.

4.2.3 Presentation of equipment that does not have an external 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 provider 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.