



SLOVENSKI STANDARD

SIST EN 301 559-1 V1.1.2:2012

01-september-2012

Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) - Aktivni medicinski vsadki majhnih moči (LP-AMI), ki delujejo v frekvenčnem območju od 2483,5 MHz do 2500 MHz - 1. del: Tehnične karakteristike in preskusne metode

Electromagnetic compatibility and Radio spectrum Matters (ERM) - Short Range Devices (SRD) - Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz - Part 1: Technical characteristics and test methods

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 301 559-1 V1.1.2:2012](https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-78b8b48e42f2/sist-en-301-559-1-v1-1-2-2012)

<https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-78b8b48e42f2/sist-en-301-559-1-v1-1-2-2012>

Ta slovenski standard je istoveten z: EN 301 559-1 Version 1.1.2

ICS:

33.060.01	Radijske komunikacije na splošno	Radiocommunications in general
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

SIST EN 301 559-1 V1.1.2:2012 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 301 559-1 V1.1.2:2012

<https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-78b8b48e42f2/sist-en-301-559-1-v1-1-2-2012>

ETSI EN 301 559-1 V1.1.2 (2012-06)



**Electromagnetic compatibility
and Radio spectrum Matters (ERM);
Short Range Devices (SRD);
Low Power Active Medical Implants (LP-AMI)
operating in the frequency range 2 483,5 MHz to 2 500 MHz;
Part 1: Technical characteristics and test methods**

Reference

DEN/ERM-TG30-300

Keywords

EMC, health, radio, SRD, testing**ETSI**

650 Route des Lucioles
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
Sous-Préfecture de Grasse (06) N° 7803/88

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 301 559-1 V1.1.2:2012<https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-78b8b48e4272/ETSI-EN-301-559-1-v1-1-2-2012>**Important notice**

Individual copies of the present document can be downloaded from:

<http://www.etsi.org>

The present document may be made available in more than one electronic version or in print. In any case of existing or perceived difference in contents between such versions, the reference version is the Portable Document Format (PDF). In case of dispute, the reference shall be the printing on ETSI printers of the PDF version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status. Information on the current status of this and other ETSI documents is available at

<http://portal.etsi.org/tb/status/status.asp>

If you find errors in the present document, please send your comment to one of the following services:

http://portal.etsi.org/chaicor/ETSI_support.asp

Copyright Notification

No part may be reproduced except as authorized by written permission.
The copyright and the foregoing restriction extend to reproduction in all media.

© European Telecommunications Standards Institute 2012.
All rights reserved.

DECT™, **PLUGTESTS™**, **UMTS™** and the ETSI logo are Trade Marks of ETSI registered for the benefit of its Members.
3GPP™ and **LTE™** are Trade Marks of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.
GSM® and the GSM logo are Trade Marks registered and owned by the GSM Association.

Contents

Intellectual Property Rights	6
Foreword.....	6
Introduction	6
1 Scope	8
2 References	8
2.1 Normative references	8
2.2 Informative references.....	9
3 Definitions, symbols and abbreviations	9
3.1 Definitions.....	9
3.2 Symbols.....	11
3.3 Abbreviations	12
4 Technical requirements and specifications.....	12
4.1 General requirements	12
4.1.1 Transmitter requirements	12
4.1.2 Receiver requirements	12
4.2 Presentation of equipment for testing purposes.....	13
4.2.1 Choice of model for testing	13
4.2.2 Spurious emission testing for composite equipment.....	13
4.2.3 Testing of equipment with alternative power levels	13
4.2.4 Presentation of equipment that does not have an external RF connector (integral antenna equipment)	14
4.2.4.1 Equipment with an internal permanent or temporary antenna connector	14
4.2.4.2 Equipment with a temporary antenna connector	14
4.2.4.3 Equipment intended to be implanted in a human body	14
4.3 Mechanical and electrical design.....	14
4.3.1 General.....	14
4.3.2 Controls	14
4.3.3 Transmitter shut-off facility	14
4.3.4 Marking	14
4.3.5 Equipment identification.....	14
4.4 Declarations by the Applicant	15
4.5 Auxiliary test equipment	15
4.6 Interpretation of the measurement results	15
5 Test conditions, power sources and ambient temperatures	15
5.1 Normal and extreme test conditions	15
5.2 Test power source.....	15
5.2.1 External test power source	15
5.2.2 Internal test power source	16
5.3 Normal test conditions.....	16
5.3.1 Normal temperature and humidity	16
5.3.2 Normal test power source	16
5.3.2.1 Mains voltage	16
5.3.2.2 Power sources	16
5.4 Extreme test conditions	17
5.4.1 Extreme temperatures	17
5.4.1.1 Procedure for tests at extreme temperatures.....	17
5.4.1.1.1 Procedure for equipment designed for continuous operation	17
5.4.1.1.2 Procedure for equipment designed for intermittent operation	17
5.4.1.2 Extreme temperature ranges.....	17
5.4.2 Extreme test source voltages.....	18
5.4.2.1 Mains voltage	18
5.4.2.2 Power sources	18
6 General conditions.....	18

6.1	Normal test signals and test modulation.....	18
6.1.1	Normal modulation test signals for data	19
6.2	Antennas.....	19
6.3	Artificial antenna.....	19
6.3.1	Artificial antenna for transmitters with 50 Ω impedance connector.....	19
6.4	Test fixture for LP-AMI-P.....	19
6.5	Test fixture for LP-AMI.....	20
6.6	Test sites and general arrangements for radiated measurements.....	20
6.7	Modes of operation of the transmitter.....	20
6.8	Measuring receiver.....	20
7	Measurement uncertainty.....	21
8	Methods of measurement and limits for transmitter parameters.....	22
8.1	Frequency error.....	22
8.1.1	Definition.....	22
8.1.1.1	Method of measurement for systems with an unmodulated carrier frequency operating mode.....	23
8.1.1.2	Method of measurement for systems with a modulated output frequency.....	23
8.1.2	Limit.....	23
8.2	Emission bandwidth measurement.....	23
8.2.1	Definition.....	23
8.2.1.1	Method of measurement.....	23
8.2.2	Limits.....	24
8.3	Effective isotropic radiated power of the fundamental emission.....	24
8.3.1	Definition.....	24
8.3.1.1	Methods of measurement.....	24
8.3.2	Limits.....	25
8.4	Spurious emissions.....	25
8.4.1	Definition.....	25
8.4.1.1	Method of measuring the effective radiated power of spurious emissions.....	25
8.4.2	Limits.....	27
8.5	Out-of-band emissions.....	27
8.5.1	Definition.....	27
8.5.2	Methods of measurement.....	27
8.5.3	Limits.....	27
8.6	Frequency stability under low voltage conditions.....	28
8.6.1	Definition.....	28
8.6.1.1	Method of measurement.....	28
8.6.2	Limits.....	28
8.7	LP-AMI-P with restricted duty cycle.....	28
8.7.1	Definitions.....	28
8.7.2	Declaration of Duty Cycle.....	28
8.7.3	Limit for duty cycle and maximum number of transmissions.....	29
9	Methods of measurement and limits for receiver parameters.....	29
9.1	Spurious radiation.....	29
9.1.1	Definition.....	29
9.1.1.1	Method of measuring the effective radiated power of spurious radiations.....	29
9.1.2	Limits.....	30
10	Requirements and Measuring Methods for Monitoring Systems.....	31
10.1	Purpose.....	31
10.2	General Remarks on the Measurement Configuration.....	31
10.3	LBT threshold power level.....	32
10.3.1	Measurement method using out-of-operating-region disturbance.....	32
10.3.2	Measurement method using frequency administration commands.....	33
10.3.3	Measurement method for LBT operation under interference condition.....	33
10.3.4	Results based on above test method.....	33
10.3.5	Limit.....	33
10.4	Monitoring system bandwidth.....	33
10.4.1	Measurement method using out-of-operating-region disturbance.....	34
10.4.2	Measurement method using frequency administration commands.....	34
10.4.3	Results based on above test method.....	34

10.5	Monitoring system scan cycle time and minimum channel monitoring period	35
10.5.1	Measurement method using out-of-operating-region disturbance	35
10.5.1.1	Scan cycle time	35
10.5.1.2	Minimum channel monitoring period	35
10.5.2	Measurement method using frequency administration commands	35
10.5.3	Results based on above test method.....	36
10.5.3.1	Scan cycle time	36
10.5.3.2	Minimum Channel Monitoring Period.....	36
10.6	Channel access based on ambient levels relative to the calculated access LBT threshold level, P_{Th}	36
10.6.1	Access based on lowest ambient level above P_{Th} using out-of-operating-region disturbance	36
10.6.2	Access based on lowest ambient level above P_{Th} using frequency administration commands	37
10.6.3	Results based on above test method.....	37
10.7	Discontinuation of AMICS session if a silent period greater than or equal to 5 seconds occurs	37
10.7.1	Measurement method.....	37
10.7.2	Results based on above test method.....	37
10.8	Use of pre-scanned alternative channel	38
10.8.1	Measurement method for alternate channel selection using out-of-operating-region disturbance.....	38
10.8.2	Measurement method for alternate channel selection using frequency administration commands	39
10.8.3	Results based on above test method.....	39
Annex A (normative): Radiated measurements		41
A.1	Test sites and general arrangements for measurements involving the use of radiated fields	41
A.1.1	Outdoor test site	41
A.1.1.1	Standard position	41
A.1.1.2	Equipment in close proximity to the human body but external to it	42
A.1.1.3	Applicative simulator.....	42
A.1.1.3.1	General matters	42
A.1.1.3.2	Vertical Human torso simulator for LP-AMI.....	42
A.1.1.3.3	Horizontal Human torso simulator for LP-AMI.....	43
A.1.2	Test antenna.....	44
A.1.3	Substitution antenna	44
A.1.4	Optional additional indoor site	45
A.2	Guidance on the use of radiation test sites	46
A.2.1	Measuring distance.....	46
A.2.2	Test antenna.....	46
A.2.3	Substitution antenna	46
A.2.4	Artificial antenna.....	46
A.2.5	Auxiliary cables.....	46
A.3	Further optional alternative indoor test site using an anechoic chamber	47
A.3.1	Example of the construction of a shielded anechoic chamber	47
A.3.2	Influence of parasitic reflections in anechoic chambers.....	47
A.3.3	Calibration of the shielded RF anechoic chamber	48
Annex B (informative): Bibliography.....		50
History		51

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: "*Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards*", which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (<http://ipr.etsi.org>).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

Foreword

This European Standard (EN) 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 purposes.

The present document is part 1 of a multi-part deliverable covering Low Power Active Medical Implants (LP-AMI), Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz as described in the systems reference document for the equipment, TR 102 655 [i.8].

Part 1: "Technical characteristics and test methods";

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

National transition dates

Date of adoption of this EN:	18 June 2012
Date of latest announcement of this EN (doa):	30 September 2012
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2013
Date of withdrawal of any conflicting National Standard (dow):	31 March 2013

Introduction

LP-AMI/LP-AMI-P equipment in the AMICS is a unique new technology, that will provide for example 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 AMICS consists of LP-AMI and/or LP-AMI-P that provide human therapeutic and diagnostic data storage and analysis capability.

The present document includes methods of measurement for Low Power Active Medical Implants (LP-AMI), and Peripherals (LP-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 (informative) bibliography; provides additional information.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 301 559-1 V1.1.2:2012](https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-78b8b48e42f2/sist-en-301-559-1-v1-1-2-2012)

<https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-78b8b48e42f2/sist-en-301-559-1-v1-1-2-2012>

1 Scope

The present document covers, for Low Power Active Medical Implants (LP-AMI), and associated Peripherals (LP-AMI-P) used in an Active Medical Implant Communications System (AMICS), the required characteristics considered necessary to efficiently use the available spectrum and serve the interests of patients with implanted devices. 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 designed to significantly reduce any interference potential between AMICS operating in the band or between AMICS and other primary or secondary users of the band. Also included in the present document is the capability of Low Duty Cycle/Low Power Access in the frequency band.

An AIMD is regulated under the AIMD Directive 90/385/EEC [i.7]: radio parts contained therein (referred to herein as LP-AMI, and LP-AMI-P for associated 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 2 483,5 MHz to 2 500 MHz 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 LP-AMI and associated peripherals radio equipment which is also addressed by CEPT/ERC/REC 70-03 [i.2] and annex 12 band f 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 LP-AMI and associated peripherals operating in the band 2 483,5 MHz to 2 500 MHz:

- for telecommand and telemetry to/from an LP-AMI in a patient's body to LP-AMI-P or between these equipments;
- for telecommand and telemetry to/from an LP-AMI to another LP-AMI 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 30 MHz.

2 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 reference document (including any amendments) 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.

2.1 Normative references

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] 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 necessary for the application of the present document but they assist the user with regard to a particular subject area.

- [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 (2011): "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] 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.5] CEPT/ERC/REC 74-01: "Unwanted Emissions in the Spurious Domain".
 - [i.6] Simulated Biological.
 - [i.7] 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.8] ETSI TR 102 655: "Electromagnetic compatibility and Radio spectrum Matters (ERM); System reference document; Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in a 20 MHz band within 2 360 MHz to 3 400 MHz".
 - [i.9] Hartsgrove and Kraszewski: "Composition And Electrical Properties Of A Liquid That Has The Electrical Properties Of Tissue", 1984.

SIST EN 301 559-1 V1.1.2:2012

<https://standards.iteh.ai/catalog/standards/sist/5139be9c-d75c-40eb-b1bf-5139be9c-d75c-40eb-b1bf>

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 Medical Implant Communication Channel (AMICC): any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in an AMICL session

NOTE: The following type of devices for Active Medical Implant Communications Systems is covered by the present document: Frequency agile devices (i.e. having implemented LBT&AFA) designed to access a minimum one of 16 channels or 8 in the case of two channels dynamically aggregated for greater instantaneous bandwidth, that are evenly distributed across the 2 483,5 MHz to 2 500 MHz band and having Duty Cycle of less than 10 % for LP-AMI-P.

Active Medical Implant Communication Link (AMICL): collection of digitally modulated transmissions that may or may not be continuous, between LP-AMIs, and LP-AMI-Ps transferring information in a communications system

Active Medical Implant Communications System (AMICS): system specifically for the purpose of providing transmission of human therapeutic digital information between one or several LP-AMI and one or several LP-AMI-P

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

NOTE: Under normal operational circumstances the AMICS are allowed to be triggered, set-up and maintained only by an LP-AMI-P acting as a master device. LP-AMI may attempt initiating the link only in cases of emergencies, described as "medical implant event".

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 there for a long period after the procedure

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

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

channel aggregation: combining two or more adjacent channels for greater bandwidth up to 2 MHz

composite equipment: any combined equipment made of two or more individual products or functions

NOTE: The individual products or functions in composite equipment might be subject to different technical standards.

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 per AMICS session, relative to a one hour period

NOTE: See clause 8.7.

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

effective isotropically radiated power (e.i.r.p.): product of the power supplied to the antenna and the antenna gain in a given direction relative to an isotropic antenna

NOTE: See clause 8.3.

emission bandwidth: measured as the width of the signal between the points on either side of centre frequency that are 20 dB down relative to the maximum level of the modulated signal

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

frequency range: range of operating frequencies over which the equipment can be adjusted

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 8.6.1.

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 an AMICS communication session according to the next available channel

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

Low Power Active Medical Implant Peripheral (LP-AMI-P) device: the radio transmitting/receiving part of an equipment that communicates indoor with one or more LP-AMI to establish an AMICL

NOTE: LP-AMI-P transmissions are allowed without limitation in cases of emergencies, described as "medical implant event".

Low Power Active Medical Implant (LP-AMI): the radio transmitting/receiving part of an AIMD inside the human body

NOTE: LP-AMI transmissions are allowed without limitation in cases of emergencies, described as "medical implant event".

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

medical implant event: occurrence recognized by a medical implant system device 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 system transmitter has been placed

NOTE: An example of medical implant event is when the LP-AMI identifies the imminent critical health condition of monitored patient. Cannot be used for scheduled data transmissions.

monitoring system: circuitry in an LP-AMI and/or LP-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) or the unoccupied sub-band or channel

out-of-band emissions: emissions on a frequency or frequencies immediately outside the necessary **emission bandwidth**, which result from the modulation process, but excluding **emissions in the spurious domain**

spurious domain emissions: emissions at frequencies separated by more than 250 % of the occupied bandwidth from the centre of the AMICC

spurious 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 may result in compromising the health and/or safety of the patient

transient power: power falling into adjacent spectrum due to switching the transmitter on and off during normal operation (e.g. cyclic keying during data transmission)

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

3.2 Symbols

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

B	bandwidth
dB	decibel

dBm	absolute power level referred to one milliwatt
E	electrical field strength
e.i.r.p.	effective isotropically radiated power
f	frequency
fc	channel centre frequency
fe	frequency under extreme conditions
G	Antenna Gain
NaCl	sodium chloride
P	power
ppm	parts per million
R	distance
PTh	maximum threshold power level (see clause 10)
T	temperature
t	time
λ	wavelength

3.3 Abbreviations

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

AC	Alternating Current
AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
AMICC	Active Medical Implant Communication Channel
AMICL	Active Medical Implant Communication Link
AMICS	Active Medical Implant Communications System
CW	Continuous Wave
DC	Direct Current
DUT	Device Under Test
EUT	Equipment Under Test
ICD	Implantable Cardiac Defibrillator
LBT	Listen Before Talk
LIC	Least Interfered Channel
LP	Low Power
LP-AMI	Low Power Active Medical Implant
LP-AMI-P	Low Power Active Medical Implant Peripheral
MD	Medical Device
r.m.s.	root mean square
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
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 2 490 MHz according to its intended function.

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 LP-AMI-P and LP-AMI device.

An appropriate human simulator and tissue substitute material for testing LP-AMI, shall be used (see clause 6.5).

Measurements shall be performed, according to the present document, on samples of equipment defined in clause 4.2.

The physical arrangement used for the testing shall be fully documented in the test report.

4.2.1 Choice of model for testing

The provider shall supply one or more samples of each model or type of transmitter (LP-AMI and/or LP-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, agreed to by the test laboratory and recorded in the test report

iteh STANDARD PREVIEW
(standards.iteh.ai)

4.2.2 Spurious emission testing for composite equipment

A composite equipment consisting of an LP-AMI-P or LP-AMI transmitter and a specific type of host equipment such as a computer for digital data recovery or programming controlling the LP-AMI-P or LP-AMI should be tested according to the following requirements.

For emission tests, the most appropriate EMC standard shall be applied to the non-radio part of the host equipment.

The emissions requirements in the applicable clauses of the present standard apply only to the LP-AMI and LP-AMI-P radio part of the composite equipment.

In the case where the radio device is integrated and cannot operate independently, emissions from the non-radio part shall be tested with the radio part disabled.

With the radio operating in transmit, receive and standby (if applicable) modes, the emission requirements of the present document shall be applied.

Additional requirements and limits for multi radio equipment are set out in the relevant radio product standards applicable to the other radio parts.

4.2.3 Testing of equipment with alternative power levels

Equipment designed to operate with different emitted 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 emissions tests shall be performed in accordance with requirements in clause 8.4.