



**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

(<https://standards.iteh.ai>)
Document Preview

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.

DECTTM, PLUGTESTSTM, UMTSTM and the ETSI logo are Trade Marks of ETSI registered for the benefit of its Members.
3GPPTM and LTETM 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 measurements41

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.....	47

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 final draft European Standard (EN) 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 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".

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

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 Standards (<https://standards.iteh.ai>) Document Preview

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

<https://standards.iteh.ai/catalog/standards/etsi/ff58b453-77d6-41d8-b31d-c9b11d4ff51b/etsi-en-301-559-1-v1-1-2-2012-06>