

**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**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/8c106e9d-eb45-482c-a635-c7166872ebb7/etsi-en-301-839-1-v1.3.1-2009-10>



Reference

REN/ERM-TG30-263-1

Keywords

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

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 2009.
All rights reserved.

DECT™, **PLUGTESTS™**, **UMTS™**, **TIPHON™**, the TIPHON logo and the ETSI logo are Trade Marks of ETSI registered for the benefit of its Members.

3GPP™ is a Trade Mark of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.

LTE™ is a Trade Mark of ETSI currently being 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	9
2.2 Informative references.....	9
3 Definitions, symbols and abbreviations	10
3.1 Definitions	10
3.2 Symbols.....	12
3.3 Abbreviations	12
4 Technical requirements and specifications.....	13
4.1 General requirements	13
4.1.1 Transmitter requirements	13
4.1.2 Receiver requirements	13
4.2 Presentation of equipment for testing purposes.....	13
4.2.1 Choice of model for testing	13
4.2.2 Testing of equipment with alternative power levels.....	13
4.2.3 Presentation of equipment that does not have an external RF connector (integral antenna equipment)	13
4.2.3.1 Equipment with an internal permanent or temporary antenna connector.....	13
4.2.3.2 Equipment with a temporary antenna connector.....	14
4.2.3.3 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	14
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 Regulated lead-acid battery power sources	16
5.3.2.3 Other 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.....	18
5.4.2 Extreme test source voltages.....	18
5.4.2.1 Mains voltage	18
5.4.2.2 Regulated lead-acid battery power sources	18
5.4.2.3 Power sources using other types of batteries.....	18
5.4.2.4 Other power sources.....	19

6	General conditions.....	19
6.1	Normal test signals and test modulation.....	19
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.....	20
6.4	Test fixture for ULP-AMI-P.....	20
6.5	Test fixture for ULP-AMI.....	20
6.6	Test sites and general arrangements for radiated measurements.....	20
6.7	Modes of operation of the transmitter.....	21
6.8	Measuring receiver.....	21
7	Measurement uncertainty.....	21
8	Methods of measurement and limits for transmitter parameters.....	22
8A	Introduction.....	22
8.1	Frequency error.....	22
8.1.1	Definition.....	23
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 carrier frequency.....	23
8.1.2	Limit.....	23
8.2	Emission bandwidth measurement.....	24
8.2.1	Definition.....	24
8.2.1.1	Method of measurement.....	24
8.2.2	Limits.....	24
8.3	Effective radiated power of the fundamental emission.....	24
8.3.1	Definition.....	24
8.3.1.1	Methods of measurement.....	25
8.3.2	Limits.....	26
8.4	Spurious emissions.....	26
8.4.1	Definition.....	26
8.4.1.1	Method of measuring the effective radiated power of spurious emissions.....	26
8.4.2	Limits.....	27
8.5	Frequency stability under low voltage conditions.....	27
8.5.1	Definition.....	27
8.5.1.1	Method of measurement.....	28
8.5.2	Limits.....	28
8.6	ULP-AMI with restricted power and duty cycle.....	28
8.6.1	Definitions.....	28
8.6.2	Declaration of Duty Cycle.....	28
8.6.3	Limit for duty cycle and maximum number of transmissions.....	28
9	Methods of measurement and limits for receiver parameters.....	28
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.....	30
10A	Purpose.....	30
10B	General Remarks on the Measurement Configuration.....	31
10.1	LBT threshold power level.....	31
10.1.1	Measurement method using out-of-operating-region disturbance.....	32
10.1.2	Measurement method using frequency administration commands.....	32
10.1.3	Results based on above test method.....	32
10.1.4	Limit.....	33
10.2	Monitoring system bandwidth.....	33
10.2.1	Measurement method using out-of-operating-region disturbance.....	33
10.2.2	Measurement method using frequency administration commands.....	34
10.2.3	Results based on above test method.....	34
10.3	Monitoring system scan cycle time and minimum channel monitoring period.....	34
10.3.1	Measurement method using out-of-operating-region disturbance.....	34
10.3.1.1	Scan cycle time.....	34

10.3.1.2	Minimum channel monitoring period	35
10.3.2	Measurement method using frequency administration commands	35
10.3.3	Results based on above test method.....	35
10.3.3.1	Scan cycle time	35
10.3.3.2	Minimum Channel Monitoring Period.....	35
10.4	Channel access based on ambient levels relative to the calculated access LBT threshold level, P_{Th}	36
10.4.1	Access based on lowest ambient level above P_{Th} using out-of-operating-region disturbance.....	36
10.4.2	Access based on lowest ambient level above P_{Th} using frequency administration commands	36
10.4.3	Results based on above test method.....	37
10.5	Discontinuation of MICS session if a silent period greater than or equal to 5 s occurs	37
10.5.1	Measurement method.....	37
10.5.2	Results based on above test method.....	37
10.6	Use of pre-scanned alternate channel	37
10.6.1	Measurement method for alternate channel selection using out-of-operating-region disturbance.....	38
10.6.2	Measurement method for alternate channel selection using frequency administration commands	39
10.6.3	Results based on above test method.....	39
Annex A (normative): Radiated measurements		40
A.1	Test sites and general arrangements for measurements involving the use of radiated fields	40
A.1.1	Outdoor test site	40
A.1.1.1	Standard position	40
A.1.1.2	Equipment in close proximity to the human body but external to it	41
A.1.1.3	Human torso simulator for ULP-AMI	41
A.1.2	Test antenna.....	42
A.1.3	Substitution antenna	42
A.1.4	Optional additional indoor site	43
A.2	Guidance on the use of radiation test sites.....	44
A.2.1	Measuring distance.....	44
A.2.2	Test antenna.....	44
A.2.3	Substitution antenna	44
A.2.4	Artificial antenna.....	44
A.2.5	Auxiliary cables.....	44
A.3	Further optional alternative indoor test site using an anechoic chamber	45
A.3.1	Example of the construction of a shielded anechoic chamber.....	45
A.3.2	Influence of parasitic reflections in anechoic chambers.....	45
A.3.3	Calibration of the shielded RF anechoic chamber	46
Annex B (normative): Technical performance of the spectrum analyser.....		48
Annex C (informative): Strategy for ULP-AMI/ULP-AMI-P in the band 402 MHz to 405 MHz (source ERM_TG30 see URL: http://www.etsi.org/)		49
Annex D (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://webapp.etsi.org/IPR/home.asp>).

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 (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the Public Enquiry 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) 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/8c106e9d-eb45-482c-a635-c7166872ebb7/etsi-en-301-839-1-v1.3.1-2009-10>

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: 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 (R&TTE Directive) [i.1].

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>.

For online referenced documents, information sufficient to identify and locate the source shall be provided. Preferably, the primary source of the referenced document should be cited, in order to ensure traceability. Furthermore, the reference should, as far as possible, remain valid for the expected life of the document. The reference shall include the method of access to the referenced document and the full network address, with the same punctuation and use of upper case and lower case letters.

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] ANSI C63.17 (1998): "American National Standard for Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (PCS) Devices".

NOTE: See http://www.techstreet.com/cgi-bin/detail?product_id=43013.

- [3] 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 ETSI deliverable 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".
- [i.7] ERC/DEC(01)17: "ERC Decision of 12 March 2001 on harmonised 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. Hartsgrrove, A. Kraszewski, and A. Surowiec as published in Bioelectromagnetics 8:29-36 (1987).

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 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)

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 emissions: emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation

NOTE: See clause 8.4.1.

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 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

3.2 Symbols

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

B	bandwidth
dB	decibel
E	electrical field strength
E _o	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
R _o	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 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.