
Reference

REN/ERM-TG30-308

Keywords

harmonised standard, radio, regulation

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

The present document can be downloaded from:

<http://www.etsi.org/standards-search>

The present document may be made available in electronic versions and/or in print. The content of any electronic and/or print versions of the present document shall not be modified without the prior written authorization of ETSI. In case of any existing or perceived difference in contents between such versions and/or in print, the only prevailing document is the print of the Portable Document Format (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

<https://portal.etsi.org/TB/ETSIDeliverableStatus.aspx>

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

<https://portal.etsi.org/People/CommiteeSupportStaff.aspx>

Copyright Notification

No part may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm except as authorized by written permission of ETSI.

The content of the PDF version shall not be modified without the written authorization of ETSI.

The copyright and the foregoing restriction extend to reproduction in all media.

© European Telecommunications Standards Institute 2017.

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
Modal verbs terminology.....	6
Introduction	7
1 Scope	8
2 References	8
2.1 Normative references	8
2.2 Informative references.....	8
3 Definitions, symbols and abbreviations	9
3.1 Definitions.....	9
3.2 Symbols.....	11
3.3 Abbreviations	11
4 Technical requirements specifications	11
4.1 Environmental profile.....	11
4.2 Conformance requirements	11
4.2.1 Transmitter requirements	11
4.2.1.1 Effective Radiated Power.....	11
4.2.1.1.1 Definition.....	11
4.2.1.1.2 Limits	11
4.2.1.1.3 Conformance	12
4.2.1.2 Out of band emissions.....	12
4.2.1.2.1 Definition.....	12
4.2.1.2.2 Limits	12
4.2.1.2.3 Conformance	12
4.2.1.3 Unwanted emissions in the spurious domain of transmitters	12
4.2.1.3.1 Definition.....	12
4.2.1.3.2 Limits	12
4.2.1.3.3 Conformance	13
4.2.1.4 Duty Cycle	13
4.2.1.4.1 Definition.....	13
4.2.1.4.2 Limits	13
4.2.1.4.3 Conformance	13
4.2.2 Receiver requirements	13
4.2.2.1 Receiver Blocking or Desensitization	13
4.2.2.1.0 Receiver Classification.....	13
4.2.2.1.1 Definition.....	14
4.2.2.1.2 Limits	14
4.2.2.1.3 Conformance	14
4.2.2.2 Receiver Spurious radiation	14
4.2.2.2.1 Definition.....	14
4.2.2.2.2 Limits	14
4.2.2.2.3 Conformance	14
4.3 Mechanical and electrical design.....	15
4.3.1 General.....	15
4.3.2 Controls	15
4.3.3 Transmitter shut-off facility.....	15
5 Testing for compliance with technical requirements.....	15
5.1 Environmental conditions for testing	15
5.1.0 General provisions	15
5.1.1 Presentation of equipment for testing purposes	15
5.1.1.0 General provisions	15
5.1.1.1 Choice of model for testing.....	15
5.1.1.2 Testing of equipment with alternate power levels.....	16

5.1.1.3	Testing of equipment that does not have an external RF connector (integral antenna equipment).....	16
5.1.1.3.0	General Provision	16
5.1.1.3.1	Equipment with an internal permanent or temporary antenna connector	16
5.1.1.3.2	Equipment with a temporary antenna connector	16
5.1.1.3.3	Equipment intended to be implanted in a human body.....	16
5.1.2	Declaration by the applicant	16
5.1.3	Auxiliary test equipment.....	16
5.1.4	Test Conditions	17
5.1.4.1	Normal and extreme test conditions.....	17
5.1.4.2	Test power source	17
5.1.4.2.0	General provisions.....	17
5.1.4.2.1	External test power source.....	17
5.1.4.2.2	Internal test power source.....	17
5.1.4.3	Normal test conditions	18
5.1.4.3.1	Normal temperature and humidity.....	18
5.1.4.3.2	Normal test power source	18
5.1.4.4	Extreme test conditions	18
5.1.4.4.1	Extreme temperatures	18
5.1.4.4.2	Extreme test source voltages	20
5.1.4.5	Normal test signals and test modulation.....	20
5.1.4.5.0	General provisions.....	20
5.1.4.5.1	Normal modulation test signals for data.....	20
5.1.4.6	Antennas	21
5.1.4.6.0	General provisions.....	21
5.1.4.6.1	Artificial antenna	21
5.1.4.6.2	Artificial antenna for transmitters with 50 Ω impedance connector.....	21
5.1.4.7	Test fixture for ULP-AMI-M-P.....	21
5.1.4.8	Test fixture for ULP-AMI-M	22
5.1.4.9	Test sites and general arrangements for radiated measurements.....	22
5.1.4.10	Modes of operation of the transmitter.....	22
5.1.4.11	Measuring receiver.....	22
5.2	Interpretation of the measurement results	23
5.3	Methods of measurement	23
5.3.1	Maximum Effective Radiated Power.....	23
5.3.2	Out of band emissions.....	24
5.3.3	Unwanted Emissions in the spurious domain	25
5.3.4	Duty Cycle.....	26
5.3.5	Receiver Blocking or desensitization.....	26
5.3.6	Receiver Spurious radiation.....	26

Annex A (normative):	Relationship between the present document and the essential requirements of Directive 2014/53/EU	28
-----------------------------	---	-----------

Annex B (normative):	Radiated Measurement	29
-----------------------------	-----------------------------------	-----------

B.1	Test sites and general arrangements for measurements involving the use of radiated fields.....	29
B.1.1	Outdoor test site	29
B.1.1.0	General remarks.....	29
B.1.1.1	Standard position	29
B.1.1.2	Equipment in close proximity to the human body but external to it.....	30
B.1.1.3	Human torso simulator for ULP-AMI-M.....	30
B.1.2	Test antenna.....	31
B.1.3	Substitution antenna	31
B.1.4	Optional additional indoor site	32
B.2	Guidance on the use of radiation test sites	33
B.2.0	General remarks	33
B.2.1	Measuring distance.....	33
B.2.2	Test antenna.....	33
B.2.3	Substitution antenna	33
B.2.4	Artificial antenna.....	33
B.2.5	Auxiliary cables.....	33

B.3	Further optional alternative indoor test site using an anechoic chamber	34
B.3.0	General remarks	34
B.3.1	Example of the construction of a shielded anechoic chamber	34
B.3.2	Influence of parasitic reflections in anechoic chambers	34
B.3.3	Calibration of the shielded RF anechoic chamber	35
Annex C (normative):	Technical performance of the spectrum analyser	37
Annex D (informative):	Bibliography	38
History		39

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Full standard:
<https://standards.iteh.ai/catalog/standards/sist/d619cb29-6944-4344-b0d1-50587418190b/etsi-en-302-510-v2.1.1-2017-01>

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 (<https://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 Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.7] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.1].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

National transposition dates	
Date of adoption of this EN:	27 December 2016
Date of latest announcement of this EN (doa):	31 March 2017
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 September 2017
Date of withdrawal of any conflicting National Standard (dow):	30 September 2018

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the [ETSI Drafting Rules](#) (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Introduction

Membrane Implants and associated peripheral equipment are a new technology in the medical field that provides, on a continuing non-invasive basis after the implant is inserted, patient related real time intravenous blood pressure information to the attending physician. This information is used for purposes of diagnosing and treating certain heart related disorders thereby reducing significantly the hospital readmission rate.

The present document is a specific product standard applicable to Ultra Low Power Active Medical Membrane Implants and Peripherals operating in the frequency range 30 MHz to 37,5 MHz.

The frequency usage conditions for the band 30 MHz to 37,5 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.10].

The present document is structured in the following way:

- 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 the technical requirements, specifications, limits and conformance relative to transmitter, receiver, and spectrum access.
- Clauses 5.1 and 5.2 specify the conditions for testing of the equipment and interpretation of the measurement results with the maximum measurement uncertainty values.
- Clause 5.3 specifies the required measurement methods. In particular clause 5.3.8 describes the monitoring system performance specifications that have been chosen to minimize harmful interference to other equipment or services and minimize the potential for disturbance to this equipment from ambient sources or other medical device users in the band.
- Annex A (normative) provides the relationship between the present document and the essential requirements of Directive 2014/53/EU [i.1].
- Annex B (normative) provides specifications concerning radiated measurements.
- Annex C (normative) provides technical performance of the spectrum analyser.
- Annex D (informative) bibliography; provides additional information.

1 Scope

The present document applies to Ultra Low Power-Active Medical Membrane Implants and Membrane Implant Peripherals as described in Directive 90/385/EEC [i.4], covering all active medical implants, that operate in a Medical Implant Communications System in the frequency band 30 MHz to 37,5 MHz.

Table 1: Ultra Low Power Active Medical Membrane Implants and Peripherals operating in the frequency band 30 MHz to 37,5 MHz

	Ultra Low Power Active Medical Membrane Implants and Peripherals service frequency bands
Transmitters - Ultra Low Power Active Medical Membrane Implants and peripherals	30 MHz to 37,5 MHz
Receivers - Ultra Low Power Active Medical Membrane Implants and peripherals	30 MHz to 37,5 MHz

The present document contains the technical requirements for characteristics of ULP-AMI-M and ULP-AMI-M-P radio equipment which are aligned with annex 12 Sub-band (d) of CEPT/ERC Recommendation 70-03 [i.6].

The frequency usage conditions for the band 30 MHz to 37,5 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.10] with the following usage restrictions:

- *"This set of usage conditions is only available to ultra-low power medical membrane implants for blood pressure measurements within the definition of active implantable medical devices in Directive 90/385/EEC."*

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Membrane Implants and peripherals used in a medical membrane implant communications system "... shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference" (article 3.2 of the Directive 2014/53/EU [i.1]). It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

2 References

2.1 Normative 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 referenced document (including any amendments) applies.

Referenced documents which are not found to be publicly available in the expected location might be found at <https://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.

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".

2.2 Informative 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 referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

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 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.
- [i.2] ETSI TR 100 028 (V1.3.1): "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".
- [i.3] Void.
- [i.4] 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.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 Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".
- [i.7] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.
- [i.8] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".
- [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] Commission Implementing Decision 2013/752/EU of 11 December 2013 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices and repealing Decision 2005/928/EC.
- [i.11] CEPT/ERC Recommendation 74-01: "Unwanted emissions in the spurious domain".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

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

Active Medical Device (AMD): any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

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

blocking: measure of the capability of the receiver to receive a wanted modulated signal without exceeding a given degradation due to the presence of an unwanted input signal at any frequencies other than those of the spurious responses in adjacent channels or bands

NOTE: See clause 4.2.2.1.

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

custom antenna: antenna built according to manufacturer's antenna design rules

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 total transmitter on time to an one hour period under repeated normal operation during the time measurement interval

NOTE 1: Whether the duty cycle is fixed or random depends on how the device is triggered.

NOTE 2: See clause 4.2.1.4.

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

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

out of band emissions: emissions resulting from the modulation process that are outside the emission bandwidth, but excluding unwanted emission in the spurious domain

NOTE: See clause 4.2.1.2.

programmer/controller: equipment used by a physician to communicate with an implanted device

radiated E-field: E-field in the direction of maximum field strength under the specified conditions of measurement

NOTE: See clause 4.2.1.1.

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

spurious radiations from receivers: emissions radiated from the antenna, the chassis and case of the receiver

NOTE: It is specified as the radiated power of a discrete signal. Included in this definition are modulation products that are outside the 20 dB down point on either side of the fundamental emission. See clause 4.2.2.2.

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

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

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

Ultra Low Power Active Medical Implant Membrane (ULP-AMI-M): active medical implant device with resonant transmission capability that operates in a ULP-AMI band and is placed inside the human body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

Ultra Low Power Active Medical Implant Membrane Peripheral(ULP-AMI-M-P): transmitter, operating outside of a human body in a ULP-AMI frequency band that transmits energy to a membrane implant with a receiver that receives information from a membrane implant for the purpose of determining pressure within the human body

unwanted emissions in the spurious domain: emissions on a frequency or frequencies which are outside the out of band domain and the level of which may be reduced without affecting the corresponding transmission of information

NOTE: Emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation. See clause 4.2.1.3.

3.2 Symbols

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

E	Electrical field strength
f	frequency
P	Power
R	Distance
t	time

3.3 Abbreviations

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

AIMD	Active Implantable Medical Device
AMD	Active Medical Device
e.r.p.	Effective Radiated Power
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
ULP-AMI-M	Ultra Low Power Active Medical Implant Membrane
ULP-AMI-M-P	Ultra Low Power Active Medical Implant Membrane Peripheral

4 Technical requirements specifications

4.1 Environmental profile

The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the declared operational environmental profile.

4.2 Conformance requirements

4.2.1 Transmitter requirements

4.2.1.1 Effective Radiated Power

4.2.1.1.1 Definition

The effective radiated power is the maximum power radiated during the interval of continuous transmission within the emission bandwidth of the EUT with the highest radiated power in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate.

4.2.1.1.2 Limits

The maximum average effective radiated power of an emission within the band 30 MHz to 37,5 MHz shall not exceed 1 milliwatt e.r.p within the emission bandwidth of the EUT. If the normal operational mode of the device uses stepped frequencies, the limit applies to the emission level of each frequency. Correction of peak power measurement by a factor determined by the duration of each pulse and the period of the pulse train at the measurement frequency is permitted to determine compliance with the limit.