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Short Range Devices (SRD); Radio equipment operating in the frequency range 315 kHz to 600 kHz for Ultra Low Power Animal Implantable Devices (ULP-AID) and associated peripherals; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Reference

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Foreword

This draft Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the combined Public Enquiry and Vote phase of the ETSI standards EN Approval Procedure.

The present document has been prepared under the Commission's standardization request C (2015) 5376 final [i.4] 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.

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):	18 months after doa

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).

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Introduction

Animal Implant Devices (AIDs) and associated peripheral equipment are a technology in the medical field that supports the development of new drugs and surgical procedures that are under development by pharmaceutical firms, medically related research college and university institutions. AIDs provide, on a continuing basis, data related to the physical effects of new drugs and the efficacy of new surgical procedures after the implant is inserted. These animals are typically housed in commercial surroundings such as laboratory environments or similar facilities such as colleges and universities.

The present document is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms and symbols and abbreviations used.
- Clause 4 specifies the requirements and limits relative to transmitter, receiver, and spectrum access.
- Clause 5 specifies the methods of measurement for the parameters specified in clause 4.
- Annex A (informative) 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 relationship between the radiating H-field and measurement distance.
- Annex D (informative) bibliography; provides additional information.

1 Scope

The present document specifies technical characteristics and methods of measurements for Ultra Low Power-Animal Implant Devices (ULP-AIDs) and Peripherals as used by industry to develop new drugs and surgical techniques that provide improved health care for the benefit of human patients. ULP-AIDs operate in a Communications System using inductive technology in the frequency band 315 kHz to 600 kHz.

Table 1: Ultra Low Power Animal Implants and Peripherals Operating in the frequency band 315 kHz to 600 kHz

	Ultra Low Power Animal Implants and Peripherals service frequency bands
Transmitters - Ultra Low Power Animal Implants and Peripherals	315 kHz to 600 kHz
Receivers - Ultra Low Power Animal Implants and Peripherals	315 kHz to 600 kHz

The present document contains the technical requirements for characteristics of ULP-AID and ULP-AID-P radio equipment which are aligned with annex 12 sub-band (c) of CEPT/ERC Recommendation 70-03 [i.3].

The frequency usage conditions for the bands 315 kHz to 600 kHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.6] with the following usage restrictions:

- *"This set of usage conditions is only available to animal implantable devices".*

The present document covers the essential requirements of article 3.2 of Directive 2014/53/EU [i.1] under the conditions identified in annex A for Ultra Low Power Animal Implants and peripherals used in an implant communications system that supports development of medically related treatments that provide improved health care for patients. 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 specific, identified by date of publication and/or edition number or version number. Only the cited version 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] CEPT/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.4] Commission Implementing Decision C (2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electro technical 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.5] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.6] 2013/752/EU: "Commission Implementing Decision 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.7] CEPT/ERC/Recommendation 74-01E: "Unwanted Emissions in the Spurious Domain".

[i.8] Radiofrequency Radiation Dosimetry Handbook (October 1986): "USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC)", Brooks Air Force Base, TX 78235-5301.

3 Definitions, symbols and abbreviations

3.1 Definitions

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

animal implant device: active implant that includes a transmitter, with or without an integral receiver, that operates in the ULP-AID band that is placed inside the body of the animal for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

artificial antenna: tuned reduced-radiating dummy load whose impedance is equal to the nominal impedance specified by the manufacturer

body worn device: physiologic sensor, holter type device, or other physiological data transfer device containing a transmitter or transceiver intended to be operated in close proximity to the animal body, which has its radio antenna external to the body, and is used to sense and/or transfer, via means of radio frequency transmission, physiological parameters or system programming information

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

dedicated antenna: removable antenna supplied and tested with the radio equipment that is designed as an indispensable part of the equipment

H-field test antenna: electric field shielded loop or equivalent antenna, with which the magnetic component of the radio frequency field can be measured

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

magnetic dipole moment: product of (Number of coil turns) × (coil area) × (coil current)

NOTE: Air coils only.

mobile station: equipment external to the animal body intended to provide communication capability to an active implant device placed within the body

programmer/controller: ULP-AID-P equipment used to communicate with an ultra low power animal implant device (ULP-AID)

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

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 transferring data at a distance

Ultra Low Power Animal Implant Device(ULP-AID): active implant transmitter that is designed to radiate RF energy in accordance with the provisions of Annex 12, band (c), to CEPT/ECC Recommendation 70-03 [i.3]

Ultra Low Power Animal Implant Device Peripheral (ULP-AID-P): peripheral to an active implant transmitter that is designed to radiate RF energy in accordance with the provisions of Annex 12, band (c), to CEPT/ECC Recommendation 70-03 [i.3]

3.2 Symbols

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

E	Electrical field strength
Eo	Reference electrical field strength (see annex B)
f	frequency
H	Magnetic field strength
Ho	Reference magnetic field strength (see annex B)
m	magnetic dipole moment
P	Power
R	Distance
Ro	Reference distance (see annex B)
t	time

3.3 Abbreviations

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

ERC	European Radio Committee
EUT	Equipment Under Test
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
ULP-AID	Ultra Low Power - Animal Implant Device
ULP-AID-P	Ultra Low Power- Animal Implant Device Peripheral

4 Technical requirements specifications

4.1 Environmental profile

4.1.0 General requirements

The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer.

4.1.1 Conformance requirements

The equipment shall comply with all the technical requirements of the present document which are identified as applicable in annex A at all times when operating within the boundary limits of the declared operational environmental profile.

4.2 Transmitter requirements

4.2.1 Radiated Field Strength

4.2.1.1 Definition

The radiated Field is defined as the average level of the emitted H-field in the direction of maximum field strength during the interval of continuous transmission within the operating frequency range of the EUT.

4.2.1.2 Limits

The maximum average field strength of an emission within the band 315 kHz to 600 kHz shall be -5 dBµA/m at 10 m. Correction of a 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.

4.2.1.3 Conformance

Conformance tests as defined in clause 5.12.2 shall be carried out.

4.2.2 Permitted range of modulation bandwidth

4.2.2.0 General

The permitted range of modulation bandwidth, as defined in clause 4.2.2.1, shall not exceed the limits in clause 4.2.2.2.

4.2.2.1 Definition

The modulation bandwidth contains all associated side bands above the following level:

a) for carrier frequencies in the range of 315 kHz to 600 kHz, at the highest level of either:

- 20 dB below the carrier; or
- the appropriate spurious limit, see clause 4.2.3.2.

Where the assigned frequency band has been divided into sub-bands by the regulatory body, the above measuring levels and bandwidths apply inside these sub-bands.

Devices whose carrier level is below the spurious limit (clause 4.2.3.2), do not have a defined modulation bandwidth.

4.2.2.2 Limits

The permitted range of the modulation bandwidth shall be within the limits of the 315 kHz to 600 kHz designated frequency band stated in annex 12 sub-band (b) of CEPT/ERC Recommendation 70-03 [i.3].

4.2.2.3 Conformance

Conformance tests as defined in clause 5.12.3 shall be carried out.