SLOVENSKI STANDARD
SIST EN 302 195 V2.1.1:2016

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Aktivni medicinski vsadki ultra majhnih moči (ULP-AMI)) in pribor (ULP-AMI-P)), ki delujejo v frekvenčnem območju 9 kHz do 315 kHz - Harmonizirani standard, ki zajema bistvene zahteve člena 3.2 direktive 2014/53/EU

Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz - Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

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Short Range Devices (SRD);
Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz
Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

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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.6] 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.2].

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:	14 June 2016
Date of latest announcement of this EN (doa):	30 September 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2017
Date of withdrawal of any conflicting National Standard (dow):	31 March 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

The present document covers Ultra Low Power Active Medical Implant (ULP-AMI) and any associated non-implantable Peripherals (ULP-AMI-P) equipment incorporating low frequency technology, which is designed to operate in the frequency range of 9 kHz to 315 kHz for the purpose of providing a digital communication link.

The present document includes methods of measurement for ULP-AMI and ULP-AMI-P incorporating attachable/detachable antenna connector(s) and/or integral antenna(s). Equipment designed for use with an integral antenna may use a temporary or permanent internal connector for the purpose of testing, provided the characteristics being measured are representative of the final product placed on the market.

If equipment already placed on the market is required to be inspected 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 the technical requirements specifications, limits and conformance relative to transmitter and receiver function.

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.

Annex A (normative) provides the relationship between the present document and the essential requirements of Directive 2014/53/EU [i.2].

Annex B (normative) provides specifications concerning radiated measurements.

Annex C (normative) provides procedures for H-field measurements at other distances than 10 m.

Annex D (informative) bibliography; provides additional information.

1 Scope

The present document applies to ULP-AMI equipment operating in the frequency range from 9 kHz to 315 kHz and any associated Peripherals (ULP-AMI-P) transmitters and receivers operating in the frequency range of 9 kHz to 315 kHz including external programmers and patient related telecommunication devices using digital modulation techniques such as, but not limited to, FSK or pulse position modulation. Analogue voice modulation is not within the scope of the present document.

The present document applies to ULP-AMI/ULP/AMI-P transmitters and receivers:

- transmitters operating in range from 9 kHz to 315 kHz with power levels ranging up to 30 dBuA/m at 10m;
- receivers operating in the range from 9 kHz to 315 kHz.

The present document applies to ULP-AMI devices:

- either with a Radio Frequency (RF) output connection and dedicated antenna, or with an integral antenna;
- for telecommand, telemetry etc. applications;
- for all types of digital modulation.

The present document covers ULP-AMI-P fixed stations (physician programmer/controllers), mobile stations (patient programmers, handheld or otherwise) and portable stations (implanted devices providing medical benefit to the implanted patient).

The present document contains the technical requirements for characteristics of ULP-AMI/ULP-AMI-P radio equipment which are aligned with annex 12 Sub-band (a) of CEPT/ERC Recommendation 70-03 [i.1].

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz *"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.2]. 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 http://docbox.etsi.org/Reference.

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The following referenced documents are necessary for the application of the present document.

Not applicable.

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] CEPT/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.2] 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.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".

[i.4] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.5] Air Force Technical Report AL/OE-TR-1996-0037: "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies", Camelia Gabriel.

[i.6] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardization request to the European Committee for Electrotechnical Standardization 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.

3 Definitions, symbols and abbreviations

3.1 Definitions

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

active medical implant: diagnostic or therapeutic device designed to be implanted in a human body containing a power source and capable of generating radio frequency energy within the 9 kHz to 315 kHz frequency band for the purpose of providing a digital communications link

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

assigned frequency: frequency within the applicable band on which the device is authorized to operate

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

custom antenna: antenna built according to providers antenna design rules

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

fixed station: equipment intended for use in a fixed location

H-field test antenna: electrically screened loop or equivalent antenna, with which the magnetic component of the 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.

medical implant device: apparatus that includes a transmitter with an integral receiver that operates in the ULP-AMI band that is placed inside the human body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

medical implant programmer/control transmitter: transmitter, operating outside of a human body in the ULP-AMI frequency band that transfers information to/from the implant after a communications link is initiated

mobile station: equipment external to the body, normally used by a patient, to provide telecommand or telemetry communication functions to a medical implant device placed within the body

patient activator: equipment intended to be used by a patient to communicate with an implanted device

portable station: equipment intended to be carried, attached or implanted in a human body that is operated at a separation distance less than 20 cm from or internal to a human body

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

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

telecommunications: use of radio communications for the transmission of data between various ULP-AMI devices

telemetry: use of radio communication for indicating or recording data at a distance

Ultra Low Power Active Medical Implant (ULP-AMI): active medical implant transmitter that is designed to radiate RF energy in accordance with the provisions of annex 12, sub-band (a) and to CEPT/ERC Recommendation 70-03 [i.1]

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P): associated medical implant programmer/control radio part located outside the human body that communicates with an ULP-AMI in accordance with the provisions of annex 12, sub-band (a) of CEPT/ERC Recommendation 70-03 [i.1]

3.2 Symbols

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

f	frequency
H	Magnetic field strength
Ho	Reference magnetic field strength
m	magnetic dipole moment
P	Power
R	Distance
Ro	Reference distance
t	time

3.3 Abbreviations

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

CEPT	European Conference of Postal & Telecommunications Administrations
EMC	ElectroMagnetic Compatibility
ERC	European Research Council
EUT	Equipment Under Test
FSK	Frequency Shift Keying
RF	Radio Frequency
SRD	Short Range Device
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral