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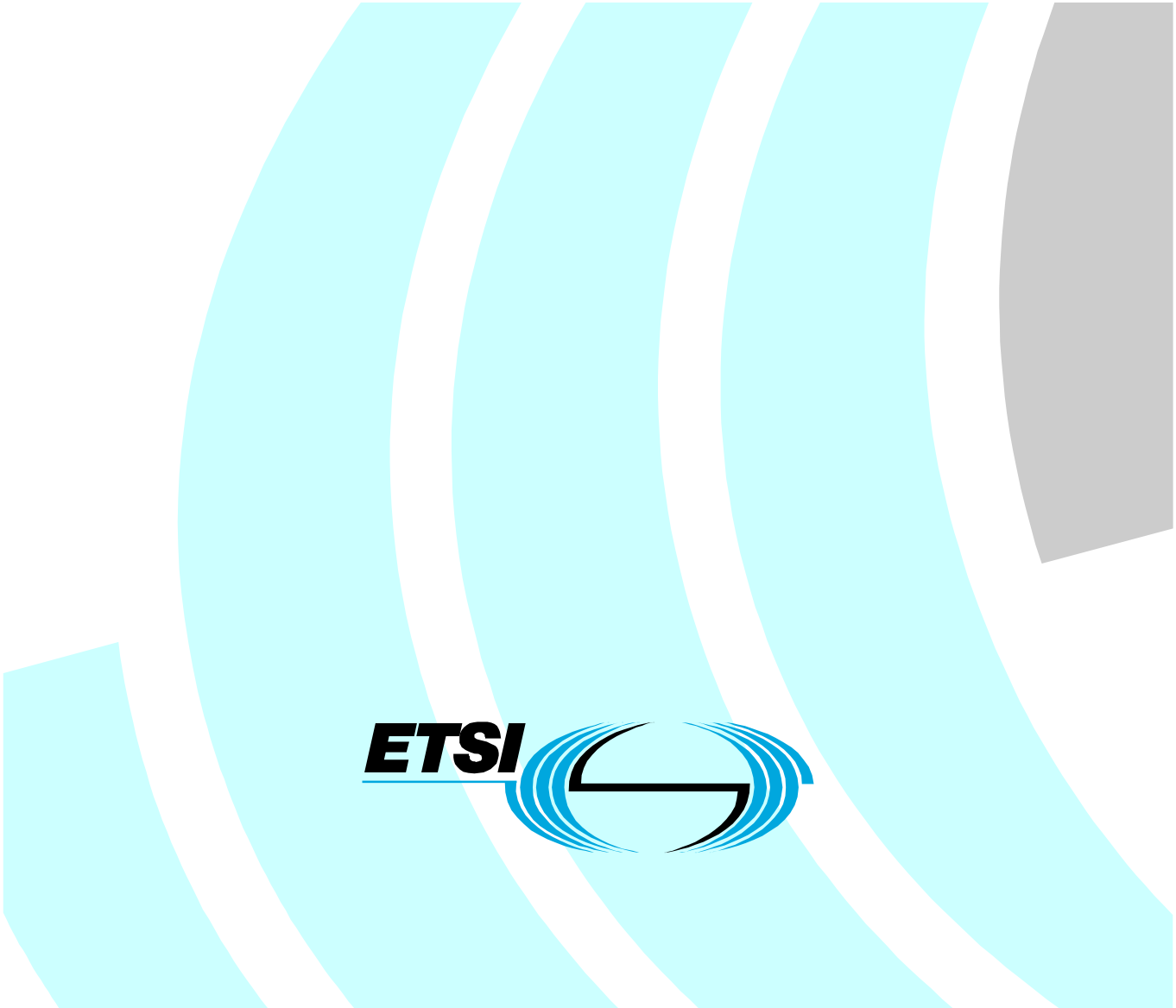
Candidate Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for ultra low power active medical implants and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive



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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 Candidate Harmonized European Standard (Telecommunications series) 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.

Technical specifications relevant to Directive 1999/5/EC [1] are given in annex A.

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [5] (as amended) laying down a procedure for the provision of information in the field of technical standards and regulations.

The present document is intended to become a Harmonized Standard, the reference of which will be published in the Official Journal of the European Communities referencing the Council Directive on the approximation of the laws of the Member States relating to Directive 1999/5/EC [1] 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 ("the R&TTE Directive").

The present document is part 2 of a multi-part deliverable covering Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants and Accessories (ULP-AMI), 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):	18 months after doa

Introduction

The present document is part of a set of standards designed to fit in a modular structure to cover all radio and telecommunications terminal equipment under the R&TTE Directive [1]. Each standard is a module in the structure. The modular structure is shown in figure 1.

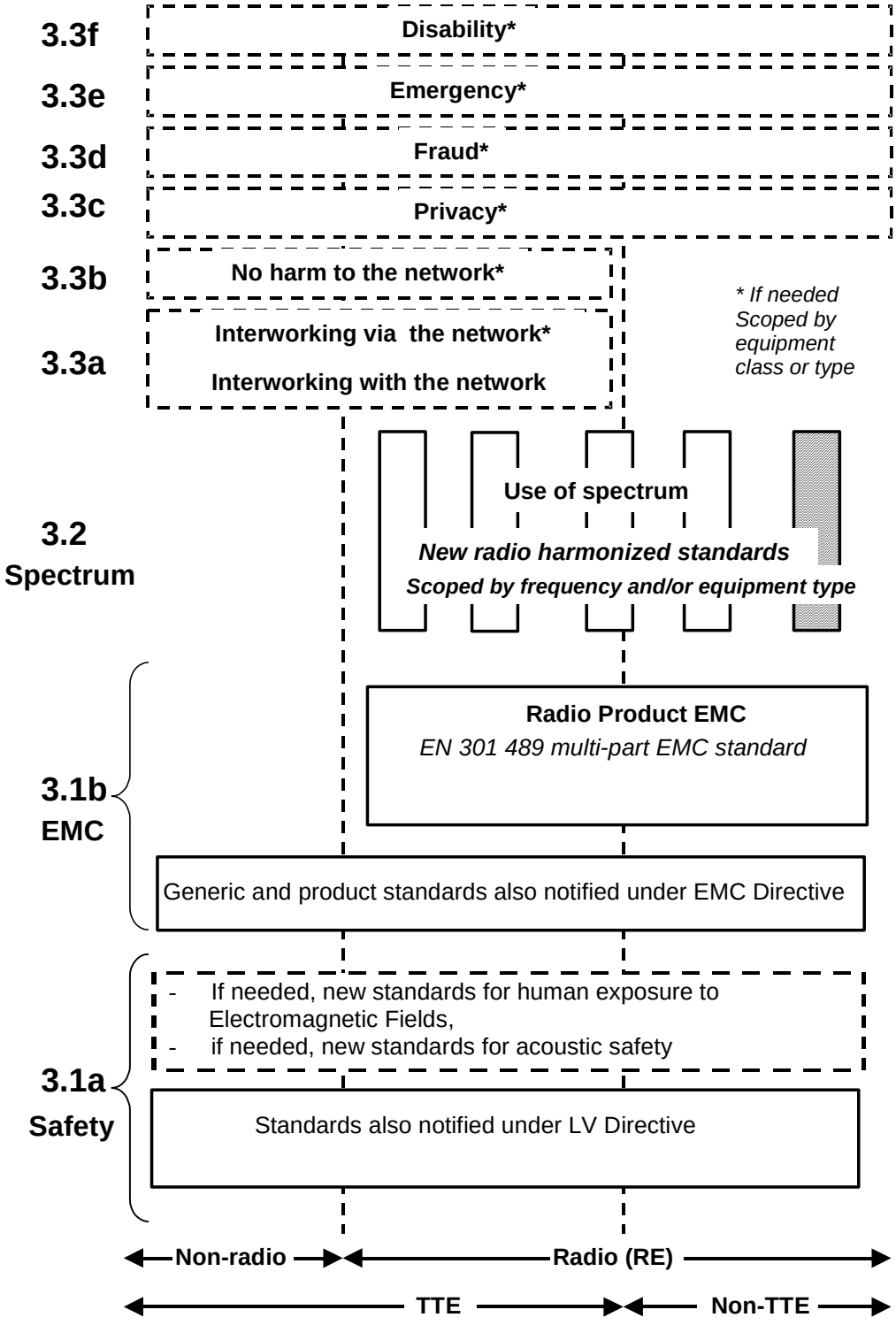

Figure 1: Modular structure for the various standards used under the R&TTE Directive

The left hand edge of the figure 1 shows the different clauses of Article 3 of the R&TTE Directive.

For article 3.3 various horizontal boxes are shown. Dotted lines indicate that at the time of publication of the present document essential requirements in these areas have to be adopted by the Commission. If such essential requirements are adopted, and as far and as long as they are applicable, they will justify individual standards whose scope is likely to be specified by function or interface type.

The vertical boxes show the standards under article 3.2 for the use of the radio spectrum by radio equipment. The scopes of these standards are specified either by frequency (normally in the case where frequency bands are harmonized) or by radio equipment type.

For article 3.1b the diagram shows EN 301 489, the multi-part product EMC standard for radio used under the EMC Directive [7].

For article 3.1a the diagram shows the existing safety standards currently used under the LV Directive [6] and new standards covering human exposure to electromagnetic fields. New standards covering acoustic safety may also be required.

The bottom of the figure shows the relationship of the standards to radio equipment and telecommunications terminal equipment. A particular equipment may be radio equipment, telecommunications terminal equipment or both. A radio spectrum standard will apply if it is radio equipment. An article 3.3 standard will apply as well only if the relevant essential requirement under the R&TTE Directive is adopted by the Commission and if the equipment in question is covered by the scope of the corresponding standard. Thus, depending on the nature of the equipment, the essential requirements under the R&TTE Directive may be covered in a set of standards.

The modularity principle has been taken because:

- it minimizes the number of standards needed. Because equipment may, in fact, have multiple interfaces and functions it is not practicable to produce a single standard for each possible combination of functions that may occur in an equipment;
- it provides scope for standards to be added:
  - under article 3.2 when new frequency bands are agreed; or
  - under article 3.3 should the Commission take the necessary decisions

  without requiring alteration of standards that are already published;
- it clarifies, simplifies and promotes the usage of Harmonized Standards as the relevant means of conformity assessment.

1 Scope

The present document applies to Ultra Low Power Active Medical Implants (ULP-AMI) transmitters and receivers:

- transmitters operating in range from 9 kHz to 315 kHz with power levels ranging up to 30 dBuA/m;
- 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;
- with or without speech.

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

All types of digital modulation for implanted radio devices and associated accessories are covered by the present document.

The power class designation is based on CEPT/ERC Recommendation 70-03 [3].

Table 1: Maximum radiated H-field or power (e.i.r.p.)

Power Class	Radiated H-field or power level
1	7 dBµA/m at 10 m
2	42 dBµA/m at 10 m
3	72 dBµA/m at 10 m (at 9 kHz to 30 kHz, descending 3 dB/octave from 30 kHz 135 kHz
4	37,7 dBµA/m at 10 m (at 135 kHz, descending 3 dB/octave from 135 kHz to 1 MHz)
	29 dBµA/m at 10 m (at 1,0 MHz descending 9 dB/octave from 1 MHz to 4,642 MHz)
5	9 dBµA/m at 10 m (4,642 MHz to 30 MHz)
Refer to annex 12, band (b)	30 dBuA/m at 10 m

The present document is intended to cover the provisions of article 3.2 of Directive 1999/5/EC (R&TTE Directive) [1] article 3.2, which states that "... radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communications and orbital resources so as to avoid harmful interference".

In addition to the present document, other ENs that specify technical requirements in respect of essential requirements under other parts of article 3 of the R&TTE Directive [1] may apply to equipment within the scope of the present document.

NOTE: A list of such ENs is included on the web site http://www.newapproach.org.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- 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.
- For a non-specific reference, the latest version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at http://docbox.etsi.org/Reference.

[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).

[2] ETSI EN 302 195-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for ultra low power active medical implants and accessories; Part 1: Technical characteristics and test methods".

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

[4] ETSI ETR 028 (1994): "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics".

[5] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

[6] Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (EMC directive).

[7] Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (LV directive).

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the R&TTE Directive [1] and EN 302 195-1 [2] apply.

3.2 Symbols

For the purposes of the present document, the symbols given in EN 302 195-1 [2] apply.

3.3 Abbreviations

For the purposes of the present document, the abbreviations given in EN 302 195-1 [2] apply.

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 Transmitter requirements

4.2.1 Radiated field strength or power

4.2.1.1 Radiated H-field

The radiated H-field, as defined in EN 302 195-1 [2], clause 7.2.1.1, shall not exceed the limits in EN 302 195-1 [2], clause 7.2.1.3, table 5.

This requirement applies to transmitters.

4.2.1.2 Radiated E-field

The radiated E-field, as defined in EN 302 195-1 [2], clause 7.2.2.1, shall not exceed the limits in EN 302 195-1 [2], clause 7.2.2.3.

This requirement applies to transmitters.

4.2.2 Permitted range of modulation bandwidth

The permitted range of operation frequencies, as defined in EN 302 195-1 [2], clause 7.3.1, shall not exceed the limits in EN 302 195-1 [2], clause 7.3.3.

This requirement applies to all transmitters.

4.2.3 Spurious emissions

The spurious emissions, as defined in EN 302 195-1 [2], clause 7.4.1, shall not exceed the limits in EN 302 195-1 [2], clause 7.4.2.2, table 6.

This requirement applies to all transmitters.

4.2.4 Duty cycle

The duty cycle, as defined in EN 302 195-1 [2], clause 7.5.1, shall not exceed the limits in EN 302 195-1 [2], clause 7.5.3, table 7 for duty cycle Class 3.

This requirement applies to all transmitters.

4.3 Receiver requirements

4.3.1 Blocking or desensitization

The blocking or desensitization, as defined in EN 302 195-1 [2], clause 8.1.1, shall not be less than the limits in EN 302 195-1 [2], clause 8.1.3, table 8.

This requirement applies to equipment class 1 and equipment class 2 receivers, as defined in EN 302 195-1 [2], clause 4.1.1.

4.3.2 Receiver spurious radiations

The spurious radiations below 30 MHz, as defined in EN 302 195-1 [2], clause 8.2.1, shall not exceed the limits in EN 302 195-1 [2], clause 8.2.1.2, table 9.

This requirement applies to all receivers.

5 Testing for compliance with technical requirements

5.1 Essential radio test suites

5.1.1 Environmental conditions for testing

5.1.1.1 Normal and extreme test-conditions

The test conditions shall be as declared by the manufacturer.

The requirements and test procedures shall be as specified in EN 302 195-1 [2], clauses 5.3 and 5.4.

5.1.1.2 Test power source

The test power source shall meet the requirements of EN 302 195-1 [2], clause 5.2.

5.1.2 Choice of samples for test suites

Measurement shall be performed, according to the present document, on samples of equipment defined in EN 302 195-1 [2], clauses 4.2.1 and 4.2.2.

5.1.3 Transmitter test suites

5.1.3.1 Effective radiated H-field, carrier current or radiated power

The test specified in EN 302 195-1 [2], clause 7.2.1.2 shall be carried out.

This test suite applies for class 1 transmitters with an integral or dedicated antenna and class 2 transmitters.

5.1.3.2 Permitted frequency range of the modulation bandwidth

The test specified in EN 302 195-1 [2], clause 7.3.2 shall be carried out.

This test suite applies to all transmitters.

5.1.3.3 Spurious emissions

The tests specified in EN 302 195-1 [2], clause 7.4.2.1 shall be carried out.

This test suite applies to all transmitters.

5.1.4 Receiver test suites

5.1.4.1 Blocking or desensitization

The tests specified in EN 302 195-1 [2], clause 8.1.2 shall be carried out. This test suite applies to Class 1 and Class 2 receivers.

5.1.4.2 Spurious radiation

The tests specified in EN 302 195-1 [2], clause 8.2.1.1 shall be carried out. This test suite applies to all receivers.

6 Interpretation of measurement results

The interpretation of the results recorded in the test report for the measurements described in the present document shall be as follows:

- the measured value related to the corresponding limit shall be used to decide whether an equipment meets the requirements of the present document;
- the value of the measurement uncertainty for the measurement of each parameter shall be separately included in the test report;
- the value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures in table 2.

Table 2: Measurement uncertainty

RF frequency	$\pm 1 \times 10^{-7}$
RF power, conducted	±1 dB
Conducted emission of receivers	±1 dB
Radiated emission of transmitter	±6 dB
Radiated emission of receiver	±6 dB
Temperature	±1°
Humidity	±5 %

For the test methods, according to the present document the uncertainty figures shall be calculated according to the methods described in the ETR 028 [4] and shall correspond to an expansion factor (coverage factor) k = 1,96 or k = 2 (which provide confidence levels of respectively 95 % and 95,45 % in case where the distributions characterizing the actual measurement uncertainties are normal (Gaussian)).

Table 2 is based on such expansion factors.

The particular expansion factor used for the evaluation of the measurement uncertainty shall be stated.

Annex A (informative): Bibliography

- 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 (AMD Directive).
- ECC Report 12 (2002): "ULTRA LOW POWER ACTIVE MEDICAL IMPLANT SYSTEMS (ULP-AMI)".
- RADIOFREQUENCY RADIATION DOSIMETRY HANDBOOK (October 1986): USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

Annex B (informative): The EN title in the official languages

Language	EN title
Czech	
Danish	
Dutch	
English	
Estonian	
Finnish	
French	
German	
Greek	
Hungarian	
Icelandic	
Italian	
Latvian	
Lithuanian	
Maltese	
Polish	
Portuguese	
Slovak	
Slovenian	
Spanish	
Swedish	

History

Document history				
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