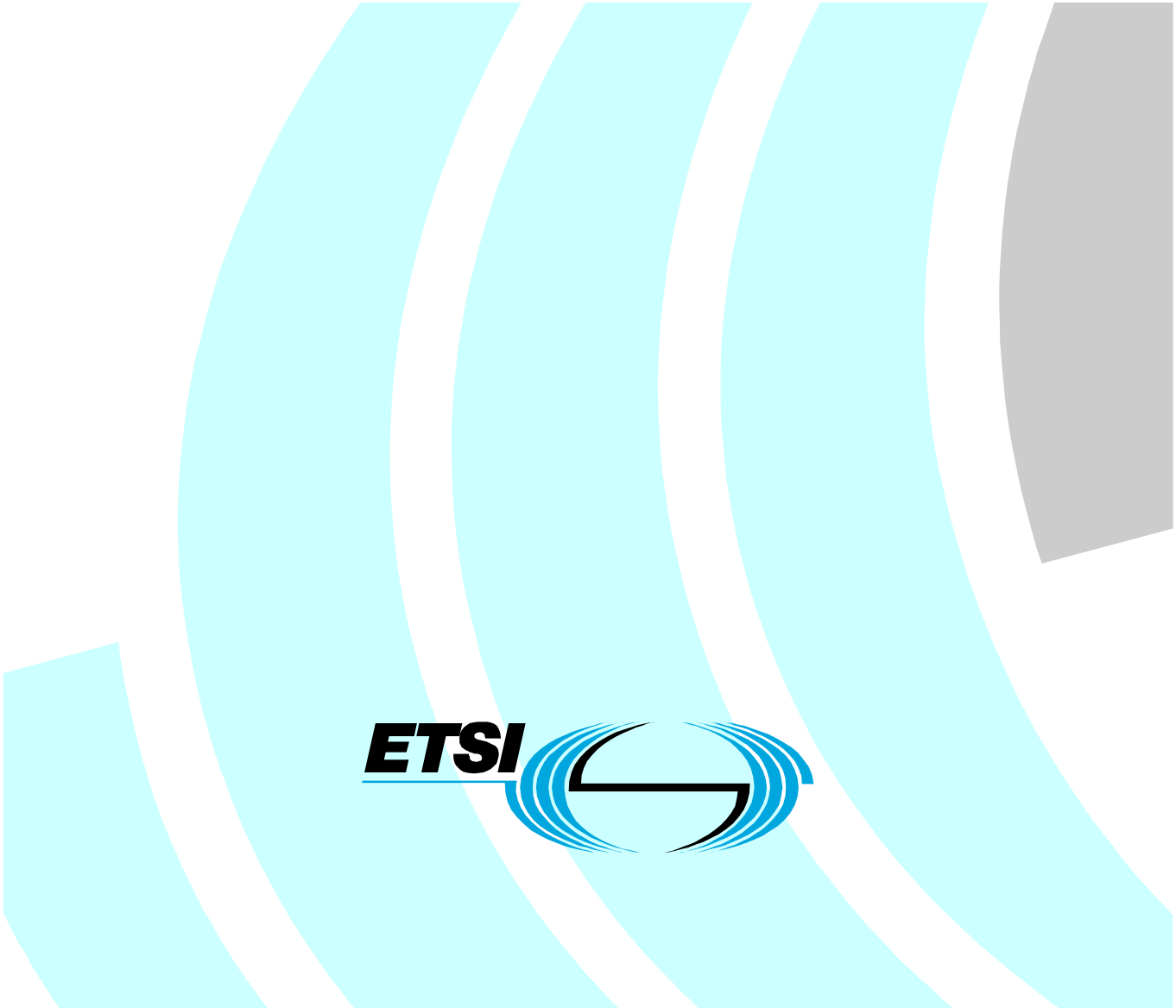
ETSI EN 301 839-2 V1.1.1 (2002-06)

Candidate Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz 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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Foreword

This Candidate Harmonized European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [7] (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 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") [1].

The present document is part 2 of a multi-part deliverable covering Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories, as identified below:

Part 1: "Technical characteristics, including electromagnetic compatibility requirements, and test methods";

Part 2: "Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

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

National transposition dates	
Date of adoption of this EN:	7 June 2002
Date of latest announcement of this EN (doa):	30 September 2002
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2003
Date of withdrawal of any conflicting National Standard (dow):	31 March 2004

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.

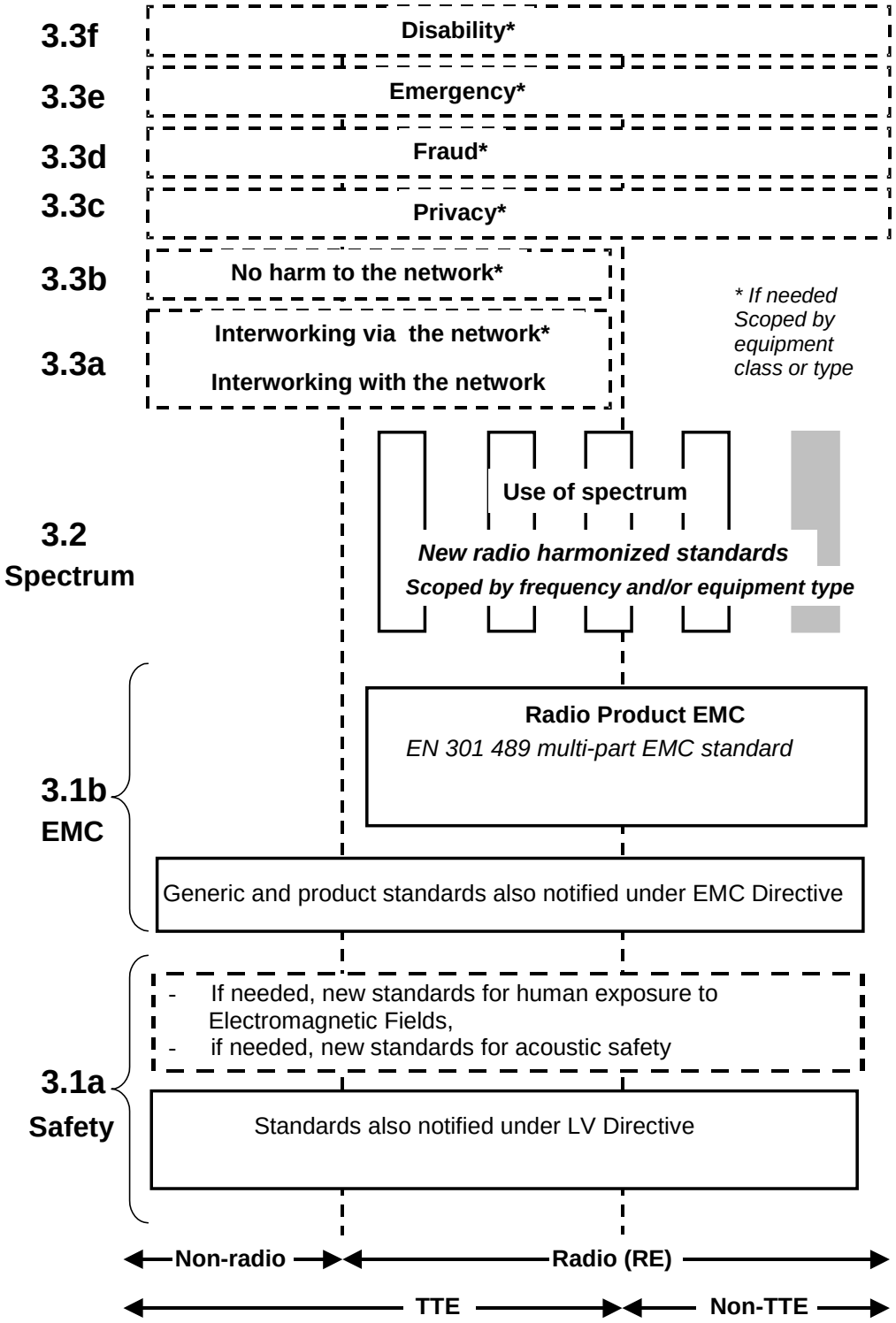

Figure 1: Modular structure for the various standards used under the R&TTE Directive

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

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 [2].

For article 3.1a the diagram shows the existing safety standards currently used under the LV Directive [3] 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 [1] 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 [1] 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) and accessories as described in Directive 90/385/EEC [4], operating in a Medical Implant Communications System (MICS) in the frequency band 402 MHz to 405 MHz.

NOTE 1: The present document applies to operation in the band 402 MHz to 405 MHz only; devices that can also operate in spectrum outside this band should also meet any applicable requirements for operation in such bands.

The present document is intended to cover the provisions of Directive 1999/5/EC [1] (R&TTE Directive) 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] will apply to equipment within the scope of the present document.

NOTE 2: 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.

[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] 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).

[3] 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).

[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.

[5] ETSI EN 301 839-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods".

[6] ETSI ETR 028 (Edition 2): "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics".

[7] 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.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the R&TTE Directive [1], and the following apply:

active medical implant: diagnostic or therapeutic device designed to be implanted in a human body containing a power source and a transceiver using the 402 MHz to 405 MHz frequency band for the purpose of providing a two way digital communications link

environmental profile: range of environmental conditions under which equipment within the scope of EN 301 839-2 is required to comply with the provisions of EN 301 839-2

Medical Implant Communications System (MICS): system specifically for the purpose of providing two way non-voice digital communications between an external programmer/control transceiver and an active medical implant transceiver or between active medical implant transceivers placed in a human body

medical implant device: apparatus that includes a transmitter with an integral receiver that operates in the ULP-AMI band from 402 MHz to 405 MHz that 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 (ULP-AMI): active medical implant transmitter or medical implant programmer/control transmitter that is designed to radiate RF energy in accordance with the provisions of annex 12 to CEPT/ERC/REC 70-03 and EN 301 839-2

3.2 Abbreviations

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

AMI	Active Medical Implant
EMC	Electro-Magnetic Compatibility
EUT	Equipment Under Test
LV	Low Voltage
MICS	Medical Implant Communications System
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
SRD	Short Range Device
TTE	Telecommunications Terminal Equipment
ULP-AMI	Ultra Low Power Active Medical Implant

4 Technical requirements specifications

4.1 Environmental profile

4.1.1 General

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

4.1.2 Temperature

Table 1: Extreme temperature ranges

Category I (General):	-20°C to +55°C
Category II (Portable equipment):	-10°C to +55°C
Category III (Equipment for normal indoor use) (see note 1):	0°C to +55°C
Category IV (Active Medical Implant transmitters) (see note 2):	+25°C to +45°C
NOTE 1: The term "equipment for normal indoor use" is taken to mean that the room temperature is controlled and the minimum indoor temperature is equal to or greater than 5°C.	
NOTE 2: The term "Active Medical Implant transmitters" refers only to equipment that is intended to be placed inside a human body during normal operation. The range of +25°C to +45°C is the core body temperature variation over which a human body can survive.	

For special applications, the manufacturer can specify wider temperature ranges than given as a minimum in table 1. This shall be reflected in the manufacturers' product literature.

The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the required operational temperature profile.

4.1.3 Power supply voltages

4.1.3.1 Mains voltage range

For equipment intended to be powered from an ac mains source, the equipment shall comply with the appropriate technical requirements of the present document at all times when operating with the mains voltage within the range nominal ±10 %.

For equipment that operates over a range of mains voltages, clause 4.1.3.4 applies.

4.1.3.2 Regulated lead-acid battery power sources

For equipment intended to be powered from regulated lead-acid battery power sources, the equipment shall comply with the appropriate technical requirements of the present document at all times when operating with the battery voltage within the range 1,3 and 0,9 multiplied by the nominal voltage of the battery (6 V, 12 V, etc.).

For float charge applications using "gel-cell" type batteries the extreme voltages shall be 1,15 and 0,85 multiplied by the nominal voltage of the declared battery voltage.

4.1.3.3 Power sources using other types of batteries

For equipment intended to be powered from other types of batteries the required lower extreme operational voltages shall be as follows:

- for equipment with a battery indicator, the end point voltage as indicated;
- for equipment without a battery indicator the following end point voltages:
  - for the Leclanché or the lithium type of battery:
    - 0,85 multiplied by the nominal voltage of the battery.
  - for the nickel-cadmium type of battery:
    - 0,9 multiplied by the nominal voltage of the battery.
- for other types of batteries or equipment, the lower extreme voltage for the discharged condition shall be declared by the equipment applicant.

The nominal voltage is considered to be the required upper extreme voltage in this case.

4.1.3.4 Other power sources

For equipment using other power sources, or capable of being operated from a variety of power sources, the extreme operational voltages shall be declared by the manufacturer.

4.2 Conformance requirements

4.2.1 Mechanical and electrical design

4.2.1.1 General

The equipment shall be designed, constructed and manufactured in accordance with sound engineering practice and with the aim of minimizing harmful disturbance to other equipment and services and should not be disturbed by harmful interference from other electronic devices. For this requirement, the provisions of clauses 10 and 12 of EN 301 839-1 [5] must be respected at a minimum.

Transmitters and receivers may be individual or combination units.

4.2.1.2 Antennas

Equipment operating in the ULP-AMI band shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna connection is made, the connector shall be a unique type to prevent use of an antenna other than a dedicated antenna supplied by the manufacturer.

4.2.1.3 Controls

Those controls that, if maladjusted, might increase the disturbing potentialities of the equipment shall not be easily accessible to the user.

4.2.1.4 Transmitter shut-off facility

If the transmitter is equipped with an automatic transmitter shut-off facility or battery-saving feature and it interferes with testing of the device, it shall be capable of being made inoperative for the purpose of testing.

4.2.2 Frequency error

4.2.2.1 Definition

The frequency error shall be as defined in EN 301 839-1 [5], clause 8.1.1.

4.2.2.2 Limits

The frequency error limits shall be as defined in EN 301 839-1 [5], clause 8.1.2.

4.2.2.3 Conformance

Conformance tests as defined in clause 5.3.1 shall be carried out.

4.2.3 Emission bandwidth

4.2.3.1 Definition

The emission bandwidth shall be as defined in EN 301 839-1 [5], clause 8.2.1.

4.2.3.2 Limits

The emission bandwidth limits shall be as defined in EN 301 839-1 [5], clause 8.2.2.

4.2.3.3 Conformance

Conformance tests as defined in clause 5.3.2 shall be carried out.

4.2.4 Effective radiated power of the fundamental emission

4.2.4.1 Definition

The effective radiated power shall be as defined in EN 301 839-1 [5], clause 8.3.1.

4.2.4.2 Limits

The effective radiated power limits shall be as defined in EN 301 839-1 [5], clause 8.3.2.

4.2.4.3 Conformance

Conformance tests as defined in clause 5.3.3 shall be carried out.

4.2.5 Spurious emissions

4.2.5.1 Definition

The spurious emissions shall be as defined in EN 301 839-1 [5], clause 8.4.1.

4.2.5.2 Limits

The spurious emissions limits shall be as defined in EN 301 839-1 [5], clause 8.4.2.

4.2.5.3 Conformance

Conformance tests as defined in clause 5.3.4 shall be carried out.

4.2.6 Frequency stability under low voltage conditions

4.2.6.1 Definition

The frequency stability under low voltage conditions shall be as defined in EN 301 839-1 [5], clause 8.5.1.

4.2.6.2 Limits

The frequency stability under low voltage conditions limits shall be as defined in EN 301 839-1 [5], clause 8.5.2.

4.2.6.3 Conformance

Conformance tests as defined in clause 5.3.5 shall be carried out.

4.2.7 Spurious radiation of receivers

4.2.7.1 Definition

The spurious radiation of receivers shall be as defined in EN 301 839-1 [5], clause 9.1.1.

4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 301 839-1 [5], clause 9.1.2.

4.2.7.3 Conformance

Conformance tests as defined in clause 5.3.6 shall be carried out.

4.2.8 Monitoring system

4.2.8.1 Definition

The monitoring system is the circuitry in a medical implant transmitter or an associated programmer/control transmitter that assures conformity with the spectrum access protocol requirements of EN 301 839-1 [5], clause 10.

4.2.8.2 Limits

The monitoring system requirements are as specified in EN 301 839-1 [5], clause 10 and subsequent clauses.

4.2.8.3 Conformance

Conformance tests as defined in clause 5.3.7 shall be carried out.

5 Testing for compliance with technical requirements

5.1 Environmental conditions for testing

Tests defined in the present document shall be carried out under the conditions appropriate to the EUT, as defined in EN 301 839-1 [5], clause 5.

5.2 Interpretation of the measurement results

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

- the measured value related to the corresponding limit will 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 included in the test report;
- the recorded value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures in table 2.

For the test methods, according to the present document, the measurement uncertainty figures shall be calculated in accordance with ETR 028 [6] 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 the case where the distributions characterizing the actual measurement uncertainties are normal (Gaussian)).

Table 2 is based on such expansion factors.

Table 2: Maximum measurement uncertainty

RF frequency	±1 x10^{-7}
Adjacent channel power	±3 dB
RF power, conducted	±0,75 dB
Conducted emission of transmitter	±4 dB
Conducted emission of receivers	±3 dB
Radiated emission of transmitter, valid up to 4 GHz	±6 dB
Radiated emission of receiver, valid up to 4 GHz	±6 dB
Conducted monitoring test system	±4 dB
Radiated monitoring test system	±6 dB
Temperature	±1°C
Humidity	±5 %

5.3 Essential radio test suites

5.3.1 Frequency error

The test for frequency error specified in EN 301 839-1 [5], clause 8.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.2.2 in order to assess compliance with the requirement.

5.3.2 Emission bandwidth

The test for emission bandwidth specified in EN 301 839-1 [5], clause 8.2.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.3.2 in order to assess compliance with the requirement.

5.3.3 Effective radiated power of the fundamental emission

The test for effective radiated power of the fundamental emission specified in EN 301 839-1 [5], clause 8.3.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.4.2 in order to assess compliance with the requirement.

5.3.4 Spurious emissions

The test for spurious emissions specified in EN 301 839-1 [5], clause 8.4.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.5.2 in order to assess compliance with the requirement.

5.3.5 Frequency stability under low voltage conditions

The test for frequency stability under low voltage conditions specified in EN 301 839-1 [5], clause 8.5.1.1 shall be carried out. The results obtained shall be compared to the limits in clause 4.2.6.2 in order to assess compliance with the requirement.

5.3.6 Spurious radiation of receivers

The test for spurious radiation of receivers specified in EN 301 839-1 [5], clause 9.1.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.7.2 in order to assess compliance with the requirement.

5.3.7 Monitoring system

The tests for monitoring system requirements specified in EN 301 839-1 [5], clause 10 and subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.8.2.

Annex A (normative): The EN Requirements Table (EN-RT)

The EN Requirements Table (EN-RT) serves a number of purposes, as follows:

- it provides a tabular summary of all the requirements;
- it shows the status of each EN-R, whether it is essential to implement in all circumstances (Mandatory), or whether the requirement is dependent on the supplier having chosen to support a particular optional service or functionality (Optional). In particular it enables the EN-Rs associated with a particular optional service or functionality to be grouped and identified;
- when completed in respect of a particular equipment it provides a means to undertake the static assessment of conformity with the EN.

Table A.1: EN Requirements Table (EN-RT)

EN Reference		**EN 301 839-2**		**Comment**
No.	**Reference**	**EN-R** (see note)	**Status**	
1	4.2.1	Mechanical and electrical design	M	
2	4.2.2	Frequency error	M	Applies to all transmitters
3	4.2.3	Emission bandwidth	M	Applies to all transmitters
4	4.2.4	Effective radiated power of the fundamental emission	M	Applies to transmitters with an integral or dedicated antenna
5	4.2.5	Spurious emissions (of transmitters)	M	Applies to all transmitters
6	4.2.6	Frequency stability under low voltage conditions	M	Applies to all battery operated equipment
7	4.2.7	Spurious radiation of receivers	M	Applies to all receivers
8	4.2.8	Monitoring system	O	Applies to all channel frequency selection systems
NOTE: These EN-Rs are justified under article 3.2 of the R&TTE Directive.				

Key to columns:

No Table entry number;

Reference Clause reference number of conformance requirement within the present document;

EN-R Title of conformance requirement within the present document;

Status Status of the entry as follows:

- M Mandatory, shall be implemented under all circumstances;
- O Optional, may be provided, but if provided shall be implemented in accordance with the requirements;
- O.n this status is used for mutually exclusive or selectable options among a set. The integer "n" shall refer to a unique group of options within the EN-RT. A footnote to the EN-RT shall explicitly state what the requirement is for each numbered group. For example, "It is mandatory to support at least one of these options", or, "It is mandatory to support exactly one of these options".

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

Language	EN title
Danish	Elektromagnetisk kompatibilitet og Radiospektrum Anliggender (ERM); Radioudstyr I frekvensområdet 402 til 405 MHz med ultra lav effekt, som benyttes I aktive medicinske implantater og hjælpeudstyr; Del 2: Harmoniseret EN son dækker de væsentlige krav I R&TTE direktivets artikel 3.2.
Dutch	Elektromagnetische compatibiliteit en radiospectrum zaken (ERM); Radio apparatuur, werkend in de frequentieband 402 - 405 MHz voor actieve medische implantaten en accessoires met ultra klein vermogen; Deel 2: Geharmoniseerde EN welke invulling geeft aan de wezenlijke vereisten, neergelegd in artikel 3.2 va de R&TTE Directive.
English	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz 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.
Finnish	Sähkömagneettinen yhteensopivuus ja radiospektriasiat (ERM); Erittäin pientehoiset radiolaiteet taajuusalueella 402 - 405 MHz aktiivisille lääketieteellisille siirrännäisille ja niiden lisälaitteille; Osa 2: Yhdenmukaistettu standardi (EN), joka kattaa R&TTE direktiivin artikla 3.2 mukaiset olennaiset vaatimukset.
French	CEM et spectre radioélectrique (ERM); Service Mobile Terrestre; Equipements radio dans la bande de fréquence 402 MHz à 405 MHz pour les implants médicaux actifs d'ultra faible puissance et accessoires; Partie 2: Norme harmonisée couvrant les exigences essentielles de l'article 3.2 de la Directive R&TTE.
German	Elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten (ERM); Funkeinrichtungen für den Einsatz im Frequenzbereich 402 MHz bis 405 MHz für aktive medizinische Implantate und Zubehör mit sehr geringer HF-Leistung; Harmonisierte Europäische Norm (EN) mit wesentlichen Anforderungen nach R&TTE-Richtlinie Artikel 3.2.
Greek	Ηλεκτρομαγνητική συμβατότητα και Θέματα Ραδιοφάσματος (ERM) - Ραδιοεξοπλισμός στην περιοχή συχνοτήτων από 402 MHz έως 405 MHz για Ενεργητικά Ιατρικά Εμφυτεύματα και Παρελκόμενα υπερχαμηλής ισχύος - Μέρος 2: Εναρμονισμένο EN για την κάλυψη των ουσιωδών απαιτήσεων του άρθρου 3.2 της Οδηγίας R&TTE.
Italian	Compatibilità elettromagnetica e Questioni relative allo spettro delle radiofrequenze (ERM); Apparecchiature radio nella gamma di frequenza 402 MHz fino a 405 MHz per accessori ed impianti medicali attivi di bassissima potenza; Parte 2: Norma armonizzata relativa ai requisiti essenziali dell'articolo 3.2 della direttiva R&TTE.
Portuguese	Assuntos de Espectro Radioelictrico e Compatibilidade Electromagnıtica (ERM); Equipamento rαdio de muito pequena potκncia para implantes mıdicos activos e seus acessσrios, operando na faixa de frequκncias de 402 MHz a 405 MHz; Parte 2: EN harmonizada cobrindo os requisitos essenciais no βmbito do Artigo 3.2 da Directiva R&TTE.
Spanish	Compatibilidad electromagnıtica y cuestiones de espectro de radiofrecuencia (ERM); Equipos radio en el rango de frecuencia entre 402 MHz y 405 MHz para Implantes y Accesorios medicos activos de potencia ultra baja; Parte 2: EN armonizada cubriendo los requisitos esenciales según el artículo 3.2 de la directiva de R&TTE.
Swedish	Elektromagnetisk kompatibilitet och radio-spektrum frågor (ERM); Radioutrustning i frekvensområdet 402 till 405 MHz för aktiva medicinska implantat och tillbehör med ultralåg effekt; Del 2: Harmoniserad EN omfattande väsentliga krav enligt artikel 3.2 i R&TTE-direktivet.

Annex C (informative): Bibliography

CEPT/ERC/REC 70-03 (1997): "Relating to the use of Short Range Devices (SRD)".

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

History

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V1.1.1	December 2000	Public Enquiry	PE 20010427: 2000-12-27 to 2001-04-27
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V1.1.1	June 2002	Publication	