ETSI EN 303 203-2 V1.1.1 (2014-11)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Medical Body Area Network Systems (MBANSs) operating in the 2 483,5 MHz to 2 500 MHz range; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

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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
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Contents

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Foreword

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

For non EU countries the present document may be used for regulatory (Type Approval) purposes.

The present document has been produced by ETSI in response to mandate M/284 issued from the European Commission under Directive 98/34/EC [i.7] as amended by Directive 98/48/EC [i.6].

The title and reference to the present document are intended to be included in the publication in the Official Journal of the European Union of titles and references of Harmonized Standard under the Directive 1999/5/EC [i.3].

See article 5.1 of Directive 1999/5/EC [i.3] for information on presumption of conformity and Harmonized Standards or parts thereof the references of which have been published in the Official Journal of the European Union.

The requirements relevant to Directive 1999/5/EC [i.3] are summarized in annex A.

The present document is part 2 of a multi-part deliverable covering Medical Body Area Network Systems (MBANSs) operating in the 2 483,5 MHz to 2 500 MHz range, as described in the systems reference document for the equipment, TR 101 557 [i.1], and as identified below:

Part 1: "Technical characteristics and test methods";

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

National transposition dates	
Date of adoption of this EN:	30 October 2014
Date of latest announcement of this EN (doa):	31 January 2015
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 July 2015
Date of withdrawal of any conflicting National Standard (dow):	31 July 2016

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**may not**", "**need**", "**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 is part of a set of standards developed by ETSI and is designed to fit in a modular structure to cover all radio and telecommunications terminal equipment within the scope of the R&TTE Directive [i.3]. The modular structure is shown in EG 201 399 [i.4].

1 Scope

The present document covers the minimum characteristics of Medical Body Area Network System (MBANS), including the spectrum monitoring and access requirements, considered necessary in order to make the best use of the available spectrum within the 2 483,5 to 2 500 MHz frequency range and to avoid harmful interference between MBANS and other users of this band. It does not necessarily include all the characteristics which may be required by a user, nor does it necessarily represent the optimum performance achievable.

The types of devices that can belong to MBANSs are on-body and off-body medical sensors, patient monitoring devices and medical actuators covered by the Medical Device Directive (Directive 93/42/EEC [i.5]).

The present document applies to the following MBANS applications which are considered to operate indoor:

- MBANS operating in the healthcare facility.
- MBANS operating in the patient's home.

The present document contains the following basic technical characteristics of MBANS radio equipment which are also addressed in Annex 2 of CEPT/ERC/REC 70-03 [i.2]:

- Healthcare facility MBANS with 1 mW maximum e.i.r.p. and not more than 10 % duty cycle over a maximum emission bandwidth of 3 MHz.
- Patient's home MBANS with 10 mW maximum e.i.r.p. and not more than 2 % duty cycle over a maximum emission bandwidth of 3 MHz.

2 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.

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

2.1 Normative references

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

[1] ETSI EN 303 203-1 (V1.1.1) (11-2014): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Medical Body Area Network Systems (MBANSs) operating in the 2 483,5 MHz to 2 500 MHz range; Part 1: Technical characteristics and test methods".

[2] ETSI TR 100 028 (V1.4.1) (12-2001): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

2.2 Informative references

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] ETSI TR 101 557: "Electromagnetic compatibility and Radio spectrum Matters (ERM); System Reference document (SRdoc); Medical Body Area Network Systems (MBANSs) in the 1 785 MHz to 2 500 MHz range".

[i.2] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.3] 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).

[i.4] ETSI EG 201 399 (V2.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); A guide to the production of Harmonized Standards for application under the R&TTE Directive".

[i.5] Directive 93/42/EEC of the Council of 14 June 1993 concerning medical devices.

[i.6] Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

[i.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, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the R&TTE Directive [i.3] and EN 303 203-1 [1], clause 3.1 apply.

3.2 Symbols

For the purposes of the present document, the symbols given in EN 303 203-1 [1], clause 3.2 apply.

3.3 Abbreviations

For the purposes of the present document, the abbreviations given in EN 303 203-1 [1], clause 3.3 apply.

4 Technical requirements and 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 provider. 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 Frequency Error

4.2.1.1.1 Definition

The frequency error shall be as defined in EN 303 203-1 [1], clause 8.1.1.

4.2.1.1.2 Limits

The frequency error shall not exceed the limits defined in EN 303 203-1 [1], clause 8.1.2.

4.2.1.1.3 Conformance

Conformance tests as defined in clause 5.3.1 of the present document shall be carried out.

4.2.1.2 Emission bandwidth

4.2.1.2.1 Definition

The emission bandwidth shall be as defined in EN 303 203-1 [1], clause 8.2.1.

4.2.1.2.2 Limits

The emission bandwidth limits shall be as defined in EN 303 203-1 [1], clause 8.2.2.

4.2.1.2.3 Conformance

Conformance tests as defined in clause 5.3.2 of the present document shall be carried out.

4.2.1.3 Effective isotropic radiated power

4.2.1.3.1 Definition

The effective isotropic radiated power shall be as defined in EN 303 203-1 [1], clause 8.3.1.

4.2.1.3.2 Limits

The effective isotropic radiated power shall not exceed the limits defined in EN 303 203-1 [1], clause 8.3.2.

4.2.1.3.3 Conformance

Conformance tests as defined in clause 5.3.3 of the present document shall be carried out.

4.2.1.4 Spurious emissions

4.2.1.4.1 Definition

The spurious emissions shall be as defined in EN 303 203-1 [1], clause 8.4.1.

4.2.1.4.2 Limits

The spurious emissions shall not exceed the limits defined in EN 303 203-1 [1], clause 8.4.2.

4.2.1.4.3 Conformance

Conformance tests as defined in clause 5.3.4 of the present document shall be carried out.

4.2.1.5 Out-of-band emissions

4.2.1.5.1 Definition

The Out-of-band emissions shall be as defined in EN 303 203-1 [1], clause 8.5.1.

4.2.1.5.2 Limits

The Out-of-band emissions shall not exceed the limits defined in EN 303 203-1 [1], clause 8.5.3.

4.2.1.5.3 Conformance

Conformance tests as defined in clause 5.3.5 of the present document shall be carried out.

4.2.1.6 Frequency stability under low voltage conditions

4.2.1.6.1 Definition

The frequency stability under low voltage conditions shall be as defined in EN 303 203-1 [1], clause 8.6.1.

4.2.1.6.2 Limits

The frequency stability under low voltage conditions shall not exceed the limits defined in EN 303 203-1 [1], clause 8.6.2.

4.2.1.6.3 Conformance

Conformance tests as defined in clause 5.3.6 of the present document shall be carried out.

4.2.1.7 Duty cycle

4.2.1.7.1 Definition

The duty cycle shall be as defined in EN 303 203-1 [1], clause 8.7.1.

4.2.1.7.2 Limits

The duty cycle shall not exceed the limits defined in EN 303 203-1 [1], clause 8.7.3.

4.2.1.7.3 Conformance

Conformance with the duty cycle requirement is declared by the provider.

4.2.2 Receiver requirements

4.2.2.1 Spurious radiation

4.2.2.1.1 Definition

The spurious radiation is defined in EN 303 203-1 [1], clause 9.1.1.

4.2.2.1.2 Limits

The spurious radiation shall not exceed the limit defined in EN 303 203-1 [1], clause 9.1.2.

4.2.2.1.3 Conformance

Conformance tests as defined in clause 5.3.7 of the present document shall be carried out.

4.2.3 Spectrum access

4.2.3.1 Definition

The spectrum access mechanisms, including LBT and AFA procedures, are defined in EN 303 203-1 [1], clause 10.

4.2.3.2 Limits

The spectrum access requirements shall be as defined in EN 303 203-1 [1], clause 10.

The monitoring system threshold power level shall not exceed the limit defined in EN 303 203-1 [1], clause 10.4.3.

4.2.3.3 Conformance

Conformance tests as defined in clause 5.3.8 of the present document 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 at representative points within the boundary limits of the declared operational environmental profile.

Where technical performance varies subject to environmental conditions, tests shall be carried out under a sufficient variety of environmental conditions (within the boundary limits of the declared operational environmental profile) to give confidence of compliance for the affected technical requirements.

5.1.1 Presentation for testing

Measurement shall be performed, according to the present document, on equipment presented for testing as defined in EN 303 203-1 [1], clause 4.

5.1.2 Test conditions

Test conditions shall be as defined in EN 303 203-1 [1], clauses 5 and 6.

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 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 included in the test report;
- the value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures given in table 3 (Measurement uncertainties up to 12,5 GHz for RF measurements) in clause 7 in EN 303 203-1 [1].

For the test methods, according to the present document, the measurement uncertainty figures shall be calculated in accordance with TR 100 028 [2] 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)).

The measurement uncertainties are given in table 3 in clause 7 in EN 303 203-1 [1].

5.3 Essential radio test suites

5.3.1 Frequency error

The test specified in EN 303 203-1 [1], clause 8.1 shall be carried out.

5.3.2 Emission bandwidth

The test specified in EN 303 203-1 [1], clause 8.2 shall be carried out.

5.3.3 Effective isotropic radiated power

The test specified in EN 303 203-1 [1], clause 8.3 shall be carried out.

5.3.4 Transmitter spurious emissions

The test specified in EN 303 203-1 [1], clause 8.4 shall be carried out.

5.3.5 Out-of-band emissions

The test specified in EN 303 203-1 [1], clause 8.5 shall be carried out.

5.3.6 Frequency stability under low voltage conditions

The test specified in EN 303 203-1 [1], clause 8.6 shall be carried out.

5.3.7 Receiver spurious emissions

The test specified in EN 303 203-1 [1], clause 9.1 shall be carried out.

5.3.8 Spectrum access

The tests for spectrum access requirements specified in EN 303 203-1 [1], clause 10 shall be carried out.

5.3.9 Normal test-conditions

The normal test procedures shall be as specified in EN 303 203-1 [1], clause 5.3.

5.3.10 Extreme test-conditions

The extreme test procedures shall be as specified in EN 303 203-1 [1], clause 5.4.

5.3.11 Test power source

The test power source shall meet the requirements of EN 303 203-1 [1], clause 5.2.

5.3.12 Choice of samples for test suites

Measurement shall be performed on samples of equipment defined in EN 303 203-1 [1], clause 4.2.

Annex A (normative): HS Requirements and conformance Test specifications Table (HS-RTT)

The HS Requirements and conformance Test specifications Table (HS-RTT) in table A.1 serves a number of purposes, as follows:

- it provides a statement of all the requirements in words and by cross reference to (a) specific clause(s) in the present document or to (a) specific clause(s) in (a) specific referenced document(s);
- it provides a statement of all the test procedures corresponding to those requirements by cross reference to (a) specific clause(s) in the present document or to (a) specific clause(s) in (a) specific referenced document(s);
- it qualifies each requirement to be either:
  - Unconditional: meaning that the requirement applies in all circumstances; or
  - Conditional: meaning that the requirement is dependent on the manufacturer having chosen to support optional functionality defined within the schedule.
- in the case of Conditional requirements, it associates the requirement with the particular optional service or functionality;
- it qualifies each test procedure to be either:
  - Essential: meaning that it is included with the Essential Radio Test Suite and therefore the requirement shall be demonstrated to be met in accordance with the referenced procedures;
  - Other: meaning that the test procedure is illustrative but other means of demonstrating compliance with the requirement are permitted.

Table A.1: HS Requirements and conformance Test specifications Table (HS-RTT)

Harmonized Standard EN 303 203-2 The following requirements and test specifications are relevant to the presumption of conformity under the article 3.2 of the R&TTE Directive [i.3]						
Requirement			**Requirement Conditionality**		**Test Specification**	
No	**Description**	**Reference: Clause No**	**U/C**	**Condition**	**E/O**	**Reference: Clause No**
1	Frequency error	4.2.1.1	U		E	5.3.1
2	Emission bandwidth	4.2.1.2	U		E	5.3.2
3	Effective isotropic radiated power	4.2.1.3	U		E	5.3.3
4	Transmitter spurious emissions	4.2.1.4	U		E	5.3.4
5	Out-of-band emissions	4.2.1.5	U		E	5.3.5
6	Frequency stability under low voltage conditions	4.2.1.6	C	Only applies to battery operated equipment	E	5.3.6
7	Duty cycle	4.2.1.7	U		-	-
8	Receiver spurious emissions	4.2.2.1	U		E	5.3.7
9	Spectrum access	4.2.3	U		E	5.3.8

Key to columns:

Requirement:

No A unique identifier for one row of the table which may be used to identify a requirement or its test specification.

Description A textual reference to the requirement.

Clause Number Identification of clause(s) defining the requirement in the present document unless another document is referenced explicitly.

Requirement Conditionality:

U/C Indicates whether the requirement is to be *unconditionally* applicable (U) or is *conditional* upon the manufacturers claimed functionality of the equipment (C).

Condition Explains the conditions when the requirement shall or shall not be applicable for a requirement which is classified "conditional".

Test Specification:

E/O Indicates whether the test specification forms part of the *Essential Radio Test Suite* (E) or whether it is one of the *Other Test Suite* (O).

NOTE: All tests whether "E" or "O" are relevant to the requirements. Rows designated "E" collectively make up the Essential Radio Test Suite; those designated "O" make up the Other Test Suite; for those designated "X" there is no test specified corresponding to the requirement. The completion of all tests classified "E" as specified with satisfactory outcomes is a necessary condition for a presumption of conformity. Compliance with requirements associated with tests classified "O" or "X" is a necessary condition for presumption of conformity, although conformance with the requirement may be claimed by an equivalent test or by manufacturer's assertion supported by appropriate entries in the technical construction file.

Clause Number Identification of clause(s) defining the test specification in the present document unless another document is referenced explicitly. Where no test is specified (that is, where the previous field is "X") this field remains blank.

Annex B (informative): Change History

Void.

Annex C (informative): Bibliography

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

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).

ETSI EN 301 489: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".

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).

ECC Report 201: "Compatibility study between MBANS operating in the 2400 - 2483.5 MHz and 2483.5 - 2500 MHz bands and other systems in the same bands or in adjacent bands".

CEPT/ERC/REC 74-01: "Unwanted Emissions in the Spurious Domain".

History

Document history			
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