ICS 33.060.20, 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA Máj 2015

STN	**Elektromagnetická kompatibilita a záležitosti rádiového spektra (ERM). Zariadenia s krátkym dosahom (SRD). Sieťové systémy v oblasti telových snímačov medicínskych údajov (MBANSs) pracujúce v rozsahu od 2 483,5 MHz do 2 500 MHz. Časť 1: Technické charakteristiky a skúšobné metódy.**	**STN EN 303 203-1 V1.1.1** 87 3203

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/15

Obsahuje: EN 303 203-1 V1.1.1:2014

120585

ETSI EN 303 203-1 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 1: Technical characteristics and test methods

Reference
DEN/ERM-TG30-304

Keywords
health, network, radio, SRD, system, testing

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
Sous-Préfecture de Grasse (06) N° 7803/88

Important notice

The present document can be downloaded from:
http://www.etsi.org

The present document may be made available in electronic versions and/or in print. The content of any electronic and/or print versions of the present document shall not be modified without the prior written authorization of ETSI. In case of any existing or perceived difference in contents between such versions and/or in print, the only prevailing document is the print of the Portable Document Format (PDF) version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status.
Information on the current status of this and other ETSI documents is available at
http://portal.etsi.org/tb/status/status.asp

If you find errors in the present document, please send your comment to one of the following services:
http://portal.etsi.org/chaircor/ETSI_support.asp

Contents

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: *"Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards"*, which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (http://ipr.etsi.org).

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

The present document is part 1 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 2015

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].

The present document describes the technical characteristics and test and performance requirements for Medical Body Area Network Systems (MBANSs) operating in the 2 483,5 MHz to 2 500 MHz frequency range.

Medical Body Area Networks are short-range low-power wireless networks, consisting of a plurality of body-worn sensor devices and/or actuator devices and a hub device placed on/around the human body. The on-body sensor devices are responsible for measuring key patient-specific information, such as the temperature, pulse, blood glucose level, electrocardiogram, blood pressure level and respiratory function readings. The hub device acts as a central controller to maintain the connections with all devices associated with its MBANS and is responsible for device association/de-association and channel selection. The hub device also typically receives the data collected from the various sensor devices on the body and may, depending on applications, process the data locally and/or further forward it to a remote central station (e.g. remote nursing station) via an appropriate wired/wireless link for centralized processing, display and storage.

Usually, MBANS devices are highly resource-constrained in terms of battery capacity, MCU capability and memory size. Therefore, simple and low-power MBANS solutions are preferred from the application point of view. Currently, most of mature low-power low-cost short-range radio solutions have spectrum efficiency around or less than 1 bps/Hz and it is expected that MBANS solutions will have similar spectrum efficiency. Also to prolong battery life, MBANS devices are expected to transmit with a limited duty cycle. The MBANS devices' duty cycle is not more than 10 % for in-hospital applications and not more than 2 % for in-home applications.

In addition to the technical specifications, the present document provides measurement methods for MBANS equipment which should support operation in healthcare facility mode or home mode, or both modes. These measurement methods are to be implemented throughout the process of manufacturing and putting onto the market. And, if the MBANS equipment is required to be checked for the purpose of market surveillance, it should be tested also in accordance with the methods of measurement specified in the present document.

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 provides details of presentation of equipment for testing.
- Clauses 5 and 6 specify the test and general conditions for testing of the equipment.
- Clause 7 defines measurement uncertainties of the test system and gives the maximum measurement uncertainty values which should not be exceeded.
- Clause 8 specifies the measurement of transmitter parameters, related to spectrum utilization, and which are required to be measured, including frequency error, emission bandwidth, e.i.r.p. of the emission, spurious and out-of-band emissions, and frequency stability.
- Clause 9 specifies measurement methods and limits for receiver parameters.
- Clause 10 provides the requirements and measuring methods for monitoring systems, primarily designed to minimize the possibility of disturbance between MBANS equipment and other users of the 2 483,5 MHz to 2 500 MHz frequency range.
- Annex A (normative) gives the specifications concerning radiated measurements.
- Annex B (informative) provides the change history.
- Annex C (informative) provides bibliography.

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 MHz to2 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.7]).

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] 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] ETSI TR 100 028 (V1.4.1): "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] CEPT/ERC/REC 74-01: "Unwanted emissions in the spurious domain".

[i.6] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.7] Directive 93/42/EEC of the Council of 14 June 1993 concerning medical devices.