ICS 33.060.20, 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA Október 2016

STN	**Zariadenia s krátkym dosahom (SRD). Systémy lekárskych telových sietí (MBANSs) pracujúce v rozsahu od 2 483,5 MHz do 2 500 MHz. Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice 2014/53/EÚ.**	**STN EN 303 203 V2.1.1** 87 3203

Short Range Devices (SRD); Medical Body Area Network Systems (MBANSs) operating in the 2 483,5 MHz to 2 500 MHz range; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

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. 09/16

Obsahuje: EN 303 203 V2.1.1:2015

123526

ETSI EN 303 203 V2.1.1 (2015-11)

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Reference
REN/ERM-TG30-311

Keywords
health, network, radio, regulation, SRD, system

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

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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 in reply to the Commission's standardisation request Commission Implementing Decision C(2015) 5376 final of 04.08.2015 to provide a 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 - also known as the Radio Equipment Directive [i.3].

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.

The present document covers 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, ETSI TR 101 557 [i.1].

National transposition dates	
Date of adoption of this EN:	2 November 2015
Date of latest announcement of this EN (doa):	29 February 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 August 2016
Date of withdrawal of any conflicting National Standard (dow):	31 August 2017

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).

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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 Radio Equipment Directive (RE-D) [i.3]. The modular structure is shown in ETSI 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. Moreover, 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 specifies the requirements and limits relative to transmitter, receiver, and spectrum access. The latter are 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.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.
- Clause 5.3 specifies the methods of measurement for the parameters specified in clause 4, related to transmitter, receiver, and spectrum access.
- Annex A (informative) provides an overview of the relationship between the present document and the essential requirements of RE-D.
- Annex B (normative) gives the specifications concerning radiated measurements.
- Annex C (informative) provides bibliography.

1 Scope

The present document contains requirements to demonstrate that Medical Body Area Network System (MBANS) *"…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.3]. The present document does not necessarily include all the requirements 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

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.

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 necessary for the application of the present document.

[1] CISPR 16-2-3 (2010) +AMD1:2010+AMD2:2014: "Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".

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] 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 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 (RE-D).

[i.4] ETSI EG 201 399 (V3.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); A guide to the production of Harmonized Standards for application under the Radio & Telecommunication Terminal Equipment Directive 1999/5/EC (R&TTE) and a first guide on the impact of the Radio Equipment Directive 2014/53/EU (RED) on Harmonized Standards".

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

[i.6] CEPT/ERC/REC 74-01: "Unwanted emissions in the spurious domain".

[i.7] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.8] 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".