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Naprave kratkega dosega (SRD) - Medicinska omrežja za merjenje parametrov človeškega telesa (MBANs), ki delujejo v frekvenčnem območju od 2483,5 MHz do 2500 MHz - Harmonizirani standard, ki zajema bistvene zahteve člena 3.2 direktive 2014/53/EU

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

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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

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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].

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Date of adoption of this EN:	2 November 2015
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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".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the RE-D [i.3] and the following apply:

Adaptive Frequency Agility (AFA): ability to determine and change to an unoccupied or least interfered sub-band or channel of operation in order to maximize spectrum utilization

composite equipment: any combined equipment made of two or more individual products or functions

NOTE: The individual products or functions in composite equipment might be subject to different technical standards.

conducted measurements: measurements that are made using a direct connection to the equipment under test

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

duly authorized healthcare professional: physician or other individual authorized by law to provide healthcare services using prescription medical devices

duty cycle: ratio, expressed as a percentage, of the maximum transmitter "on" time monitored over one hour, relative to a one hour period

NOTE: See clause 4.2.1.7.

effective isotropically radiated power (e.i.r.p.): product of the power supplied to the antenna and the antenna gain in a given direction relative to an isotropic antenna

NOTE: See clause 4.2.1.3.

effective radiated power: power radiated within the emission bandwidth of the EUT in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate

emission bandwidth: measured as the width of the signal between the points on either side of centre frequency that are 20 dB down relative to the maximum level of the modulated signal

frequency administration commands: commands, exclusively intended for testing purposes, which place the equipment under test in a specific frequency configuration, such as a channel or sub-set of channels

frequency error: difference between the nominal frequency as measured on the equipment under test and under normal test conditions and the frequency under extreme conditions

frequency range: range of operating frequencies over which the equipment can be adjusted

NOTE: See also clause 4.2.1.1.1.

frequency stability under low voltage condition: ability of the equipment to remain on the nominal operating frequency when the battery voltage falls below the lower extreme voltage level

NOTE: See also clause 4.2.1.6.1.

healthcare facility: hospital or other establishment where medical care is provided by authorized healthcare professionals

healthcare facility mode: operational regime by which MBANS equipment is intended to be operated exclusively within healthcare facilities

home mode: operational regime by which MBANS equipment is intended to be operated exclusively within patient residences

integral antenna: permanent fixed antenna, which may be built-in, designed as an indispensable part of the equipment

LBT threshold power level: ambient signal power level above which the monitoring system selects spectrum for MBANS transmissions according to the next available channel

Least Interfered Channel (LIC): channel, among the available channels, that has the lowest potential for causing disturbance to or receiving disturbance from other users of the band

Listen Before Talk (LBT): combination of the listen mode followed by the talk mode

listen mode: action taken by an interrogator to detect an unoccupied sub-band or channel

medical actuator: medical device responsible for performing an action on the human body for diagnostic and/or therapeutic purposes (e.g. an infusion pump)

MBANS hub: medical device that selects the frequency of operation, gives instructions to participating devices of the MBANS, and controls system operation

Medical Body Area Network System (MBANS): low power radio system used for the indoor transmission of non-voice data to and from medical devices for the purposes of monitoring, diagnosing and treating patients as prescribed by duly authorized healthcare professionals

NOTE: A MBANS consists of one or more on-body wireless medical sensor devices and/or medical actuator devices that can communicate with a monitoring device placed on/around the human body. Such monitoring devices, in their role of MBANS hub, display and process physiological parameters from MBANS devices and may also forward them (e.g. to a central nurse station) by using wired or wireless technologies other than MBANSs. MBANS hubs control MBANS devices for the purpose of providing monitoring, diagnosis and treatment of patients. Implantable devices are not part of MBANSs.

medical device: any instrument, apparatus, appliance, material or other article, falling under the Medical Device Directive (Directive 93/42/EEC [i.5]), whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

medical sensor: medical device responsible for the collection of physiological parameters for diagnostic and/or therapeutic purposes

monitoring system: circuitry that assures conformity with the spectrum access protocol requirements based on Listen Before Talk, Adaptive Frequency Agility and selection of the Least Interfered Channel for operation (LIC) or the unoccupied sub-band or channel

out-of-band emissions: emissions on a frequency or frequencies immediately outside the necessary emission bandwidth, which result from the modulation process, but excluding emissions in the spurious domain

Power Spectral Density (PSD): amount of the total power inside the measuring receiver bandwidth expressed in dBm/Hz

provider: manufacturer, or his authorized representative or the person responsible for placing the equipment on the market

spurious domain emissions: emissions at frequencies separated by more than 250 % of the occupied bandwidth from the centre of the occupied spectrum

spurious radiations from the receiver: components at any frequency, generated and radiated by active receiver circuitry and the antenna

NOTE: See clause 4.2.2.1.1.

talk mode: transmission of intentional radiation by a transmitter

3.2 Symbols

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

B	emission bandwidth
dB	decibel
dBm	absolute power level referred to one milliwatt
e.i.r.p.	effective isotropically radiated power
f	frequency
f_c	channel centre frequency
fe	frequency under extreme conditions
G	Antenna Gain
P	power
ppm	parts per million
R	distance
P_{Th}	maximum threshold power level (see clause 4.2.3)
T	temperature
t	time
λ	wavelength (lambda)

3.3 Abbreviations

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

AC	Alternating Current
AFA	Adaptive Frequency Agility
BW	Bandwidth
CW	Continuous Wave
DC	Direct Current
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
LBT	Listen Before Talk
LIC	Least Interfered Channel
MBANS	Medical Body Area Network System
MCU	Micro Controller Unit
PSD	Power Spectral Density
r.m.s.	root mean square
RBW	Resolution BandWidth
RE-D	Radio Equipment Directive
RF	Radio Frequency
SRD	Short Range Device