
**Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) -
Naprave kratkega dolega - Medicinska omrežja za merjenje parametrov
človeškega telesa (MBANs), ki delujejo v frekvenčnem območju od 2 483,5 MHz do
2 500 MHz - 1. del: Tehnične karakteristike in preskusne metode**

Electromagnetic compatibility and Radio spectrum Matters (ERM) - Short Range Devices
(SRD) - Medical Body Area Network Systems (MBANs) operating in the 2 483,5 MHz to
2 500 MHz range - Part 1: Technical characteristics and test methods

ITeH STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 303 203-1 V1.1.1:2014](https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc16a/sist-en-303-203-1-v1-1-1-2014)

<https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc16a/sist-en-303-203-1-v1-1-1-2014>

Ta slovenski standard je istoveten z: EN 303 203-1 Version 1.1.1

ICS:

33.060.99	Druga oprema za radijske komunikacije	Other equipment for radiocommunications
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN 303 203-1 V1.1.1:2014

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 303 203-1 V1.1.1:2014

<https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc16a/sist-en-303-203-1-v1-1-1-2014>

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 303 203-1 V1.1.1:2014

<https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc142/ETSI-EN-303-203-1-v1-1-1-2014>

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/chaicor/ETSI_support.asp

Copyright Notification

No part may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm except as authorized by written permission of ETSI.

The content of the PDF version shall not be modified without the written authorization of ETSI.

The copyright and the foregoing restriction extend to reproduction in all media.

© European Telecommunications Standards Institute 2014.

All rights reserved.

DECT™, **PLUGTESTS™**, **UMTS™** and the ETSI logo are Trade Marks of ETSI registered for the benefit of its Members. **3GPP™** and **LTE™** are Trade Marks of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.

GSM® and the GSM logo are Trade Marks registered and owned by the GSM Association.

Contents

Intellectual Property Rights	6
Foreword.....	6
Modal verbs terminology.....	6
Introduction	7
1 Scope	8
2 References	8
2.1 Normative references	8
2.2 Informative references.....	8
3 Definitions, symbols and abbreviations	9
3.1 Definitions	9
3.2 Symbols.....	11
3.3 Abbreviations	11
4 Technical requirements and specifications.....	12
4.1 General requirements	12
4.1.1 Transmitter requirements	12
4.1.2 Receiver requirements	12
4.2 Presentation of equipment for testing purposes.....	12
4.2.1 Choice of model for testing	12
4.2.2 Spurious emission testing for composite equipment.....	12
4.2.3 Testing of equipment with alternative power levels.....	13
4.2.4 Presentation of equipment that does not have an external RF connector (integral antenna equipment).....	13
4.2.4.1 Equipment with an internal permanent or temporary antenna connector.....	13
4.2.4.2 Equipment with a temporary antenna connector.....	13
4.3 Mechanical and electrical design.....	13
4.3.1 General.....	13
4.3.2 Controls	13
4.3.3 Transmitter shut-off facility.....	13
4.4 Declarations by the Applicant	13
4.5 Auxiliary test equipment	14
4.6 Interpretation of the measurement results	14
5 Test conditions, power sources and ambient temperatures	14
5.1 Normal and extreme test conditions	14
5.2 Test power source.....	14
5.2.1 External test power source	14
5.2.2 Internal test power source	14
5.3 Normal test conditions.....	15
5.3.1 Normal temperature and humidity	15
5.3.2 Normal test power source	15
5.3.2.1 Mains voltage.....	15
5.3.2.2 Other power sources.....	15
5.4 Extreme test conditions	15
5.4.1 Extreme temperatures	15
5.4.1.1 Procedure for tests at extreme temperatures.....	15
5.4.1.1.1 Procedure for equipment designed for continuous operation	16
5.4.1.1.2 Procedure for equipment designed for intermittent operation	16
5.4.1.2 Extreme temperature ranges.....	16
5.4.2 Extreme test source voltages.....	17
5.4.2.1 Mains voltage.....	17
5.4.2.2 Other power sources.....	17
6 General conditions.....	17
6.1 Normal test signals and test modulation.....	17

6.1.1	Normal modulation test signals for data	17
6.2	Antennas	17
6.3	Test fixture	17
6.4	Test sites and general arrangements for radiated measurements	18
6.5	Modes of operation of the transmitter	18
6.6	Measuring receiver	18
7	Measurement uncertainty	19
8	Methods of measurement and limits for transmitter parameters	20
8.1	Frequency error	20
8.1.1	Definition	20
8.1.1.1	Method of measurement for systems with an unmodulated carrier frequency operating mode	20
8.1.1.2	Method of measurement for systems with a modulated output frequency	21
8.1.2	Limits	21
8.2	Emission bandwidth measurement	21
8.2.1	Definition	21
8.2.1.1	Method of measurement	21
8.2.2	Limits	22
8.3	Effective isotropic radiated power of the fundamental emission	22
8.3.1	Definition	22
8.3.1.1	Methods of measurement	22
8.3.2	Limits	23
8.4	Spurious emissions	23
8.4.1	Definition	23
8.4.1.1	Method of measuring the effective radiated power of spurious emissions	23
8.4.2	Limits	25
8.5	Out-of-band emissions	25
8.5.1	Definition	25
8.5.2	Methods of measurement	25
8.5.3	Limits	27
8.6	Frequency stability under low voltage conditions	27
8.6.1	Definition	27
8.6.1.1	Method of measurement	27
8.6.2	Limits	27
8.7	MBANS with restricted duty cycle	27
8.7.1	Definitions	27
8.7.2	Declaration of Duty Cycle	28
8.7.3	Limit for duty cycle and maximum number of transmissions	28
9	Methods of measurement and limits for receiver parameters	28
9.1	Spurious radiation	28
9.1.1	Definition	28
9.1.1.1	Method of measuring the effective radiated power of spurious radiations	28
9.1.2	Limits	29
10	Requirements and Measuring Methods for Monitoring Systems	30
10.1	Purpose	30
10.2	General Remarks on the Measurement Configuration	30
10.3	Adaptive Frequency Agility	30
10.4	LBT threshold power level	32
10.4.1	Measurement method using frequency administration commands	32
10.4.2	Results based on above test method	32
10.4.3	Limit	32
10.5	Monitoring system bandwidth	32
10.6	Minimum channel monitoring period	32
10.6.1	Measurement method using frequency administration commands	33
10.6.2	Results based on above test method	33
10.6.3	Limit	33
10.7	Channel access based on ambient levels relative to the calculated access LBT threshold level, P_{Th}	33
10.7.1	Accessing an unoccupied channel	33
10.7.2	Results accessing an unoccupied channel	34
10.7.3	Accessing the Least Interfered Channel	34

10.7.4	Results accessing the LIC	34
10.7.5	Limits.....	34
Annex A (normative):	Radiated measurements	35
A.1	Test sites and arrangements for radiated measurements	35
A.1.1	Outdoor test site	35
A.1.2	Indoor test site	35
A.1.3	Shielded anechoic test site.....	36
A.2	Antennas.....	38
A.2.1	Test antenna.....	38
A.2.2	Substitution antenna	38
A.3	Test practice and auxiliary test equipment	39
A.3.1	Measuring distance.....	39
A.3.2	Auxiliary cables.....	39
Annex B (informative):	Change History	40
Annex C (informative):	Bibliography.....	41
History		42

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 303 203-1 V1.1.1:2014

<https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc16a/sist-en-303-203-1-v1-1-1-2014>

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".

(standards.iteh.ai)
National transposition dates

Date of adoption of this EN:	SIST EN 303 203-1 V1.1.1:2014	30 October 2014
Date of latest announcement of this EN (doa):	https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-83250386c16a/sist-en-303-203-1-v1-1-1-2014	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: <http://catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc16a/sist-en-303-203-1-v1-1-1-2014>

- 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 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.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.

iTeh STANDARD PREVIEW

2 References (standards.iteh.ai)

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.

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and definitions 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 8.7.

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 8.3.

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 unit 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 devices 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 8.1.1.

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 8.6.1.

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)

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.

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

medical device: any instrument, apparatus, appliance, material or other article, falling under the Medical Device Directive (Directive 93/42/EEC [i.7]), 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

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 9.1.1.

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
f_e	frequency under extreme conditions
G	Antenna Gain
P	power
ppm	parts per million
R	distance
P_{Th}	maximum threshold power level (see clause 10)
T	temperature
t	time
λ	wavelength (lambda)

STANDARD PREVIEW
(standards.iteh.ai)

3.3 Abbreviations

SIST EN 303 203-1 V1.1.1:2014

<https://standards.iteh.ai/catalog/standards/sist/57912457-e128-4b8c-adae-8525038bc16a/sist-en-303-203-1-v1-1-1-2014>

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
DUT	Device Under Test
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
RF	Radio Frequency
SRD	Short Range Device
VSWR	Voltage Standing Wave Ratio