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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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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".