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Foreword

This Technical Report (TR) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

ETSI ERM has in preparation a System Reference Document, TR 102 889-2 [i.29] for Technical characteristics for SRD equipment for wireless industrial applications using technologies different from Ultra-WideBand (UWB). ETSI has also identified two of the candidate frequency bands (2 360 MHz to 2 400 MHz and 2 483,5 MHz to 2 500 MHz) proposed for MBANSs as candidate bands for these wireless industrial applications. Both applications are license exempt SRD applications but can be both considered as critical within their environment and hence why the usual SRD bands are not intended to be used by these systems.

A MBANS is intended to be used mainly in hospitals, or at a later stage of the treatment, at the patient's home. In any case the environment for the application is far away from the application of e.g. wireless sensors used for machine automation in a factory environment. This is why these two applications in such clearly defined but totally different environments will not harmfully interfere with each other.

The CEPT is requested to give due consideration on both requests simultaneously. Obviously, the possible impact on other services remains to be studied.

Executive summary

MBANSs are intended to provide wireless networking of multiple body sensors and actuators used for monitoring patient physiological parameters, patient diagnosis and patient treatment, primarily in healthcare facilities as well as in other healthcare monitoring situations such as ambulances and the patient's home. Use of MBANSs holds the promise of improved quality and efficiency of patient care by reducing or eliminating a wide array of hardwired, patient-attached cables used by present monitoring technologies.

Providing spectrum for MBANS operations would serve the public interest in the light of the significant healthcare benefits provided by MBANSs. The present document provides an overview of MBANS technologies that can address this opportunity.

The proponents (Philips, Zarlink, Texas Instruments and Dutch Ministry of Economic Affairs Agriculture and Innovation) have an interest in addressing a growing market for MBANS services in the frequency range 1 785 MHz to 2 500 MHz but are concerned that no specific regulatory guidance from CEPT/ECC exists for administrations wishing to implement the MBANSs.

The present document gives an overview of a MBANS, its technical parameters, possible implementation scenarios, including co-existence scenarios with the incumbent services and economical and societal benefits.

A spectrum of 40 MHz between 1 785 MHz and 2 500 MHz is required for MBANS operation. A 40 MHz spectrum designation plays a key role in enabling MBANS devices achieve harmonized coexistence with other services. It enables MBANS equipment to use low-power and limited duty cycle, while providing sufficient space for MBANSs to avoid interference to/from other services. It is also needed to support MBANS co-existence in high-density deployment scenarios. The proposed 40 MHz designation affords meaningful frequency diversity that would allow MBANS devices to use lower transmission power and therefore mitigate potential interference to other services.

Initially, only the band 2 360 MHz to 2 400 MHz has been proposed by the SRdoc to be considered for use by MBANS. However, during the SRdoc development process, the 1 785 MHz to 1 805 MHz, 2 400 MHz to 2 483,5 MHz and 2 483,5 MHz to 2 500 MHz bands were suggested as other candidate bands to be considered for designation for MBANS use. A preliminary assessment of these bands is given in clause 8.

It is proposed that the bigger portion (75 %) of the required operational band should be used only inside the healthcare facilities such as hospitals, clinics, emergency rooms etc. (indoor use), and the smaller portion (25 %) should be used both inside and outside the boundaries of healthcare facilities (indoor and outdoor).

Frequency aspects of MBANS are discussed in greater detail in clause 8 and annex A.

The required emission bandwidth is up to 5 MHz for proper operation of the MBANS. The emission bandwidth used would depend on the data-rate requirement of the particular MBANS application. For high data-rate applications (e.g. 250 kbps and beyond), the bandwidth would be 3 MHz to 5 MHz. For low data-rate applications, the bandwidth would be 1 MHz to 3 MHz.

For MBANS transmitters operating within the healthcare facility sub-band (indoor), the maximum transmitted power over the emission bandwidth is 1 mW e.i.r.p. For MBANS transmitters operating within the location independent sub-band, the maximum transmitted power over the emission bandwidth is 20 mW e.i.r.p.

The proposed MBANSs will operate at limited duty cycle to reduce power consumption and avoid interference to other services. It is expected that the duty cycle of a MBANS for in-hospital use will not be more than 25 %. For location independent MBANS applications, such as in patient homes, a much lower duty cycle of usually less than 2 % is expected.

Listen-Before-Talk (LBT), Adaptive Power Control (APC), Automatic Repeat Request (ARQ), channel coding, spectrum spreading, frequency agility, and other mechanisms may be used by MBANSs for efficient operation and compatibility with other services.

A detailed technical description of MBANS, including the required bandwidth, power and channel access mechanisms, is provided in clause 7.

The proponents are of the opinion that designation of the required spectrum for the use of MBANSs based on the proposed technical and operational characteristics will not be a source of interference to current users of the band. MBANS is proposed to operate as license exempt SRD.

Introduction

The present document has been developed to support the co-operation between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Postal and Telecommunications Administrations (CEPT).

The present document is intended to define the required frequency range by describing the system and providing an estimation of the radio spectrum demand for Medical Body Area Network Systems (MBANSs). It thus intends to lay the foundation for industry to quickly implement innovative systems within Europe while avoiding harmful interference with other services and systems and providing spectrum identical with other parts of the world, thus allowing European industry to be more competitive.

1 Scope

The present document describes Medical Body Area Network Systems (MBANSs), which will require a change of the present frequency designation within CEPT.

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.30]). Implantable devices do not fall within the scope of MBANSs.

The present document includes in particular:

- Market information.
- Technical information including expected sharing and compatibility issues.
- Regulatory issues.

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 reference 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.

Not applicable.

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] GE Healthcare, Ex Parte Comments of GE Healthcare in Docket 06-135, December 2007.

NOTE: Available at http://fjallfoss.fcc.gov/ecfs/document/view.action?id=6519820996.

[i.2] Notice of Proposed Rulemaking in 08-59.

NOTE: Available at http://fjallfoss.fcc.gov/ecfs/document/view?id=7020036990.

[i.3] ERC Report 25: "The European table of frequency allocations and utilisations in the frequency range 9 kHz to 3000 GHz".

[i.4] ITU-R Radio Regulations, Edition 2008; Article 5.

[i.5] ERC/REC 62-02 E (Tromsø 1997): "Harmonised frequency band for civil and military airborne telemetry applications".

[i.6] Revised ERC/REC 25-10: "Frequency ranges for the use of temporary terrestrial audio and video SAP/SAB links" (incl. ENG/OB).