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Technical Report

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

Reference
DTR/ERM-TG30-100

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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).

[i.7] ETSI EN 301 783: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Land Mobile Service; Commercially available amateur radio equipment".

[i.8] ETSI EN 302 064: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless Video Links (WVL) operating in the 1,3 GHz to 50 GHz frequency band".

[i.9] ERC/REC 70-03: "Relating to the use of short range devices (SRD)".

[i.10] ERC Report 038: "Handbook on radio equipment and systems video links for ENG/OB use".

[i.11] ECC Report 149: "Analysis on compatibility of Low Power-Active Medical Implant (LP-AMI) applications within the frequency range 2360-3400 begin-of-the-skype-highlightingend-of-the-skype-highlighting MHz, in particular for the band 2483.5-2500 MHz, with incumbent services".

[i.12] ERC/REC 74-01: "Unwanted emissions in the spurious domain".

[i.13] ITU-R Recommendation M.1459 for interference protection.

[i.14] White paper: "Together for Health: A Strategic Approach for the EU 2008-2013".

NOTE: Available at http://ec.europa.eu/health-eu/doc/whitepaper_en.pdf.

[i.15] MedWiN Physical Layer Proposal, IEEE P802.15-09-0329-00-0006, May 2009.

NOTE: Available at https://mentor.ieee.org/802.15/dcn/09/15-09-0329-00-0006-medwin-physical-layer-proposal-documentation.pdf.

[i.16] K.Y.Yazdandoost, et al: "Channel Model for Body Area Network (BAN)", IEEE P802.15-08-0780-09-0006.

NOTE: Available at https://mentor.ieee.org/802.15/dcn/08/15-08-0780-09-0006-tg6-channel-model.pdf.

[i.17] Akram Alomainy, et al: "Statistical Analysis and Performance Evaluation for On-Body Radio Propagation with Microstrip Patch Antennas", IEEE Transactions on antennas and propagation, Vol. 55, No. 1, pp 245-248, January 2007.

[i.18] http://www.airlink101.com/download/download_links/7ma-manual.pdf.

[i.19] M.Singh, Z. Lei, F. Chin, and Y.S. Kwok: "A cyclic odd bit inversion code mapping and modulation scheme for the IEEE 802.15.4b 868 MHz band", IEEE Wireless Communications and Networking Conference (WCNC) vol. 4, pp. 1806-1810, 2006.

[i.20] John Pinkney, and Abu Sesay: "Characterization of the On-Body Wireless Channel at 2.4 and 5.8 GHz", IEEE VTC-2005-Fall.

[i.21] X. Liang, and I. Balasingham: "Performance analysis of the IEEE 802.15.4 based ECG monitoring network", Proceedings of the seventh IASTED international conferences Wireless and Optical Communications, 2007.

[i.22] "Eurostat population projections", published on the International Day of Older Persons, 29 September 2006.

[i.23] Standard IEEE 802.15.4: "Wireless medium access control (MAC) and physical layer (PHY) specifications for low-rate wireless personal area networks (WPANs)", September 2006.

[i.24] Philips, GE, AFTRCC Joint FCC Ex Parte 01-14-2011.

NOTE: Available at http://fjallfoss.fcc.gov/ecfs/document/view?id=7021025926.

[i.25] Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz).

[i.26] Chipcon Products from Texas Instruments, CC2400 datasheet.

NOTE: Available at: http://focus.ti.com/lit/ds/symlink/cc2400.pdf.

[i.27] Chipcon Products from Texas Instruments, CC2420 datasheet.

NOTE: Available at: http://focus.ti.com/lit/ds/symlink/cc2420.pdf.

[i.28] Andrew Fort: "Body area communications: Channel characterization and ultra-wideband system-level approach for low power", Nov. 2007.

NOTE: Available at: http://wwwir.vub.ac.be/elec/PhDpdf/mainAndrew.pdf.

[i.29] ETSI TR 102 889-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); System Reference Document; Short Range Devices (SRD); Part 2: Technical characteristics for SRD equipment for wireless industrial applications using technologies different from Ultra-Wide Band (UWB)".

[i.30] Council Directive 93/42/ECC of 14 June 1993 concerning medical devices.

[i.31] ETSI EN 301 908-19: "IMT cellular networks; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive; Part 19: OFDMA TDD WMAN (Mobile WiMAX) TDD User Equipment (UE)".

[i.32] ETSI EN 301 908-20: "IMT cellular networks; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive; Part 20: OFDMA TDD WMAN (Mobile WiMAX) TDD Base Stations (BS)".

[i.33] ETSI EN 301 473: "Satellite Earth Stations and Systems (SES); Aircraft Earth Stations (AES) operating under the Aeronautical Mobile Satellite Service (AMSS)/Mobile Satellite Service (MSS) and/or the Aeronautical Mobile Satellite on Route Service (AMS(R)S)/Mobile Satellite Service (MSS)".

[i.34] ETSI EN 301 441: "Satellite Earth Stations and Systems (SES); Harmonized EN for Mobile Earth Stations (MESs), including handheld earth stations, for Satellite Personal Communications Networks (S-PCN) in the 1,6/2,4 GHz bands under the Mobile Satellite Service (MSS) covering essential requirements under Article 3.2 of the R&TTE directive".

[i.35] ETSI EN 300 440: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 1: Technical characteristics and test methods".

[i.36] ETSI EN 300 328: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive".

[i.37] ETSI EN 300 761: "Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Short Range Devices (SRD); Automatic Vehicle Identification (AVI) for railways operating in the 2,45 GHz frequency range".

[i.38] ETSI EN 300 422: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless microphones in the 25 MHz to 3 GHz frequency range".

[i.39] ETSI EN 301 840: "Electromagnetic compatibility and Radio Spectrum Matters (ERM); Digital radio microphones operating in the CEPT Harmonized band 1 785 MHz to 1 800 MHz".

[i.40] ETSI EN 301 357: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Cordless audio devices in the range 25 MHz to 2 000 MHz".

[i.41] ETSI EN 300 454: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Wide band audio links".

[i.42] ECC/DEC/(07)04 of 21 December 2007 on free circulation and use of mobile satellite terminals operating in the Mobile-Satellite Service allocations in the frequency range 1-3 GHz.

[i.43] ECC/DEC/(07)05 of 21 December 2007 on exemption from individual licensing of land mobile satellite terminals operating in the Mobile-Satellite Service allocations in the frequency range 1-3 GHz.

[i.44] ERC/DEC/(97)03 of 30 June 1997 on the Harmonised Use of Spectrum for Satellite Personal Communication Services (S-PCS) operating within the bands 1610-1626.5 MHz, 2483.5-2500 MHz,1980-2010 MHz and 2170-2200 MHz.

[i.45] ERC/DEC/(97)05 of 30 June 1997 on Free Circulation, Use and Licensing of Mobile Earth Stations of Satellite Personal Communications Services (S-PCS) Operating within the Bands 1610-1626.5 MHz, 2483.5-2500 MHz, 1980-2010 MHz and 2170-2200 MHz within the CEPT.

[i.46] IEEE 802.15.6: "IEEE Standard for Information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements; Part 15.6".

[i.47] Frost & Sullivan 2009: "The European Market for Wireless patient Monitoring devices".

[i.48] ECC/DEC/(02)06 of 15 November 2002 on the designation of frequency band 2500 - 2690 MHz for UMTS/IMT-2000.

[i.49] ERC/DEC/(01)07 of 12 March 2001 on harmonised frequencies, technical characteristics and exemption from individual licensing of Short Range Devices used for Radio Local Area Networks (RLANs) operating in the frequency band 2400 - 2483.5 MHz.

[i.50] ERC/DEC/(01)08 of 12 March 2001 on harmonised frequencies, technical characteristics and exemption from individual licensing of Short Range Devices used for Movement Detection and Alert operating in the frequency band 2400 - 2483.5 MHz.

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and definitions apply:

acuity: characteristic of a medical condition that expresses the degree to which the condition has either or both of a rapid onset and a short course

NOTE: Emergency rooms, operating rooms and intensive care units are typical high acuity settings, whereas general wards and the patient's home are low acuity settings.

contention-based protocol: protocol that allows multiple devices to share the same spectrum by defining the events that occurs when two or more transmitters attempt to simultaneously access the same channel and establishing rules by which a transmitter provides reasonable opportunities for other transmitters to operate on the same channel

NOTE: Such a protocol may consist of procedures for initiating new transmissions, procedures for determining the state of the channel (available or unavailable), and procedures for managing retransmissions in the event of an occupied channel.

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

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

hub: MBANS device functioning as a patient monitor that selects frequency of operation, gives instructions to participating devices of the MBANS, collects data and controls system operation

Medical Body Area Network System (MBANS): low power radio system used for the 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

patient monitor: medical device used to display, analyze, and process the vital signs of a patient

NOTE: It may also be used to control medical actuators such as respirator devices or infusion pumps. Two types of patient monitor can be identified: (1) bedside patient monitors, non-portable and designed to be placed next to the patient's bed (2) portable patient monitors, designed to be worn (e.g. attached to the belt) or carried by the patient.

telecare: delivery of health and social care to individuals within the home or wider community, with the support of systems enabled by ICT

telehealth: synonym of remote healthcare, e.g. remote patient monitoring

3.2 Symbols

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

dB	deciBel
dBi	deciBel relative to an isotropic radiator
dBm	deciBel relative to 1 mW
ppm	parts per million

3.3 Abbreviations

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

3GPP	3rd Generation Partnership Project
ACK	Acknowledgement
AFTRCC	Aerospace and Flight Test Radio Coordinating Council
APC	Adaptive Power Control
ARQ	Automatic Repeat reQuest
ATS	Aeronautical Telemetry System
AVI	Automatic Vehicle Identification
AWGN	Additive White Gaussian Noise
BAN	Body Area Network
BER	Bit Error Rate
BP	Blood Pressure
BW	Bandwidth
BWS	Broadband Wireless Systems
CEPT	Conference of European Postal and Telecommunications Administration
CGC	Complementary Ground Component
CSMA	Carrier Sense Multiple Access
CSMA/CA	Collision Sensing Multiple Access / Collision Avoidance
DARC	Deutscher Amateur Radio Club
DSSS	Direct Sequence Spread Spectrum
e.i.r.p.	effective isotropically radiated power
e.r.p.	effective radiated power
EC	European Commission
ECA	European Common Allocation
ECC	Electronics Communications Committee
ECG	Electrocardiogram
EMG	Electromyogram
ER	Emergency Room
ETSI	European Telecommunications Standards Institute
EU	European Union
E-UTRA	Evolved Universal Terrestrial Radio Access
FCC	Federal Communications Commission
FM	Frequency Management
FSK	Frequency Shift Keying
FWA	Fixed Wireless Access
GDP	Gross Domestic Product
GFSK	Gaussian Frequency Shift Keying

GSM	Global System for Mobile communications
IARU VHF	International Amateur Radio Union - Very High Frequency
IARU	International Amateur Radio Union
ICT	Information and Communication Technologies
ICU	Intensive Care Unit
IEEE	Institute of Electrical and Electronics Engineers
IL	Implementation Loss
IMEC	Interuniversity Microelectronics Centre
IMT	International Mobile Telecommunications
ISM	Industrial, Scientific and Medical
ITU	International Telecommunication Union
K_B	Boltzmann constant
LBT	Listen-Before-Talk
LP-AMI	Low Power Active Medical Implant
MAC	Medium Access Control
MBANS	Medical Body Area Network System
MCU	Micro Controller Unit
MFCN	Mobile/Fixed Communication Networks
MSS	Mobile Satellite Service
NF	Noise Figure
NICT	National Institute of Information and Communications Technology
NPRM	Notice of Proposed Rulemaking
OJEU	Official Journal of the European Union
O-QPSK	Offset Quadrature Phase Shift Keying
OR	Operating Room
PER	Packet Error Rate
PHY	Physical / Physical Layer
PT	Project Team
QoS	Quality of Service
QPSK	Quadrature Phase Shift Keying
REP	Report
RF	Radio Frequency
RFID	Radio Frequency Identification
RR	Radio Regulations
RX	Receiver (Reception)
SAP/SAB	Services Ancillary to Programme making / Services Ancillary to Broadcasting
SAR	Specific Absorption Rate
SNR	Signal-to-Noise Ratio
SpO2	Saturation of Peripheral Oxygen
SRD	Short Range Device
TDD	Time Division Duplex
TFES	Task Force for Harmonized Standards for IMT-2000
TX	Transmitter (Transmission)
TX/RX	Transmission/Reception
TX-RX	Transmitter to Receiver
UHF	Ultra High Frequency
UMTS	Universal Mobile Telecommunications System
US	United States
UTRA	Universal Terrestrial Radio Access
UWB	Ultra Wide Band
VHF	Very High Frequency
WG	Working Group
WiMAX^{TM}	Worldwide interoperability for Microwave Access

4 Comments on the System Reference Document

4.1 Statements by ETSI Members

Siemens objects against the restriction to "non-voice" services in the present document: System Reference document (SRdoc) on "Medical Body Area Network Systems (MBANSs) in the 1 785 MHz to 2 500 MHz range" for the following reasons:

1) It is entirely feasible to fulfil all requirements for audio and voice transmission within the restrictions described in the present document. Limited duty-cycle, enforcement of indoor operation for the lower sub-band, contention-based protocol and power limitations could be implemented in the same way as for the proposed data transmission. E.g. the requirements for ECG transmission are similar to the ones for transmitting a stereo audio signal.

2) The missing ability to transmit audio and voice signals blocks relevant MBANS applications from the market. Neither applications, that are related to monitoring audio signals (recording heart beatings) nor applications related hearing impairments (e.g. hearing aids, cochlear implants) are feasible. Hence, a significant market is lost in which synergies could have been leveraged to provide health care at reasonable cost.

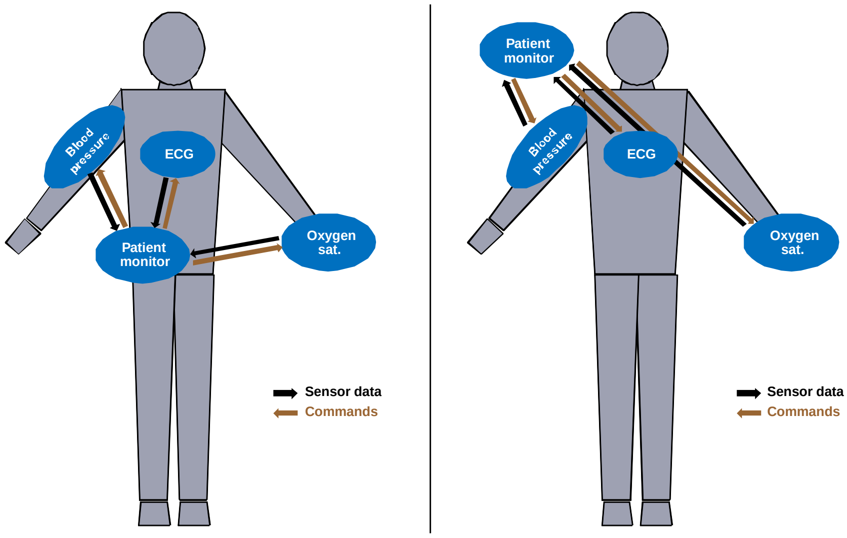
3) Public address systems, that are recognized key in integrating people with hearing impairments into public life, are forbidden in the context of the present document although they would technically fit into the described MBANSs. This limitation would stop the progress within the Hearing Aid Industry to converge to a digital public address system standard as requested by the EC.

5 Presentation of the system or technology

5.1 Definition and applications

Today, existing technologies allow for wired solutions for monitoring patient vital signs such as oxygen saturation (SpO2), blood pressure, electrocardiogram (ECG) and blood glucose, as well as controlling actuators such as ventilators and infusion pumps. On-body sensors—measuring vital signs of a patient—and actuators are wired up to, typically, a bedside patient monitor. This bundle-of-wires situation limits the mobility of patients and reduces their comfort, adversely affecting their recovery times. Workflow delays are also introduced due to care givers moving tethered patients. The first wireless patient monitoring solutions operating in the generic SRD band from 2 400 MHz to 2 483,5 MHz have recently been introduced to overcome the disadvantages of wired solutions. However the increasingly intensive use of this band by other applications (such as WiFi, Bluetooth® and ISM equipment) will tend to prevent such systems from offering the required reliability as their use increases within healthcare facilities.

Medical Body Area Network System (MBANS) is a low power radio system used for the transmission of non-voice data to and from medical devices for the purposes of monitoring, diagnosing and treating patients by duly authorized healthcare professionals. A MBANS consists of one or more on-body wireless sensors—to simultaneously collect multiple vital sign parameters—and/or medical actuator devices that can communicate with a monitoring device placed on/around (up to 10 meters from) the human body. Such monitoring devices, in their role of MBANS hub, display and process vital sign 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 also control MBANS devices for the purpose of providing monitoring, diagnosis and treatment of patients. Implantable devices are not part of MBANSs. It is expected that, as most typical configuration, a MBANS hub will be associated to only one patient; in the same fashion as a patient monitor is typically wired up to a single patient today. Two MBANS examples are depicted in figure 1.



a) MBANS with portable patient monitor b) MBANS with bedside patient monitor

Figure 1: MBANS examples

MBANSs aim at enabling wireless monitoring, diagnosis and treatment of patients, and are hence defined in the context of medical applications only.

Although the first MBANSs will be mostly deployed in hospitals, they will later extend into the patient's home in order to enable home healthcare. Whereas MBANS-enabled in-hospital patient monitoring may be applied to high acuity and low acuity medical conditions, home monitoring will obviously be restricted to the latter. An example of a high acuity condition (i.e. acute health state) would be that of a patient that lies in the intensive care unit (ICU) right after an invasive surgery operation. An example of a low acuity condition would be that of a patient a few days after surgery and who has a low relapse probability but is still under the doctor's observation. The last phase of low acuity monitoring is currently taking place in hospital but will increasingly occur also at the patient's home. In addition to in hospital (or emergency care facility) and at the patient's home, MBANSs are also expected to be used in ambulances for monitoring patient vital signs during patient transportation. It is intended that deployment and usage of MBANSs will be at the direction of healthcare professionals. This restriction applies to MBANS operation in both healthcare facilities and out of healthcare facilities (e.g. at patient's home).

5.2 Societal benefits

Europe, as well as other regions in the world, are facing a serious ageing problem. The number of people in the EU aged 65+ will grow by 70 % and the 80+ age group will grow by 170 % by 2050 due to low birth rates and increasing longevity [i.22]. These changes are likely to raise demand for healthcare significantly and, at the same time, decrease the working population. This may increase healthcare spending by 1 % to 2 % of GDP in EU Member States by 2050 and on average this would amount to about a 25 % increase in healthcare spending as a share of GDP [i.14].

The introduction of MBANSs will enable wireless patient monitoring, diagnosis and treatment solutions that fully meet clinical reliability standards. These solutions would entail clear societal benefits, both in terms of quality of healthcare and reduction of healthcare costs.

A higher quality of healthcare would be achieved due to:

- Shorter recovery times by increased patient mobility and comfort
- Shorter recovery times by early discharge to the patient's home
- Earlier detection of worsening health state (previous to a preventable acute condition) by extension of patient monitoring to most, if not all, patients in many hospitals

- Lower risk of cross-infections by easier disinfection of wireless patient sensors (no wires to disinfect and easier sensor handling) or by deployment of disposable wireless sensors

At the same time—and strongly related to the higher quality of healthcare—cost reductions would be achieved due to:

- Lower treatment costs by shorter overall recovery times
- Lower hospital lodging costs by shorter hospital stays
- Lower number of cost-intensive high acuity cases by early detection and prevention
- Lower sepsis- and infection related costs by lower risk of cross infections
- Improved hospital workflow and efficiency of nursing staff

6 Market information

6.1 Wireless patient monitoring - general trends

According to "The European Market for Wireless patient Monitoring devices" (Frost & Sullivan 2009) [i.47], the market for wireless patient monitoring devices can be segmented as the markets for:

a) wireless assisted living devices;

b) wireless vital signs measurement devices; and

c) portable personal health (wellness) devices.

In 2008 this represented a European market for wireless patient monitoring devices of $ 89,9 million. The market is still in the initial growth stage with a market growth rate of 7,7 % (2008).

The factors driving the market are:

- Preference of elderly population to age at home

  The increase in the per cent of people over the age of 65 years and above is the basic factor driving the healthcare market over the years. There exists a trend where European citizens prefer to stay at home for a comfortable living. This trend is the biggest driver of the need for equipment like wireless assisted living devices and wireless vital signs measurement. These devices help the physicians to keep a check on patients' health on a regular basis and provide timely treatment as and when necessary.

- Shift towards telecare to reduce cost in hospital treatment

  Budget constraints are forcing hospital management to save cost per hospital bed. Healthcare providers look upon telecare and telehealth as effective solutions for treating and monitoring patients at home. This helps in reducing the cost and providing timely treatment. Telecare also diminishes the chances of the spread of infections. This method of monitoring vital signs using telecare devices is user-friendly, safe and comfortable to the patient.

- Awareness regarding well being of citizens

  Well being of its citizens is gaining prominence among the countries in Europe. Government organisations in some countries are funding projects to provide telecare solutions. The governments recognise the advantages of providing telecare facilities. The support of the governments in popularising telecare by implementing policy, regulations and forwarding the required budgets is fuelling the growth of the market of equipment for well being.

Figure 2 shows the revenue forecasts for the total European wireless patient monitoring devices market from 2005 to 2015.

The market is expected to grow steadily during the forecast period as the preference for elderly people to age at home increases along with the rise in awareness regarding telecare products in the western European countries.

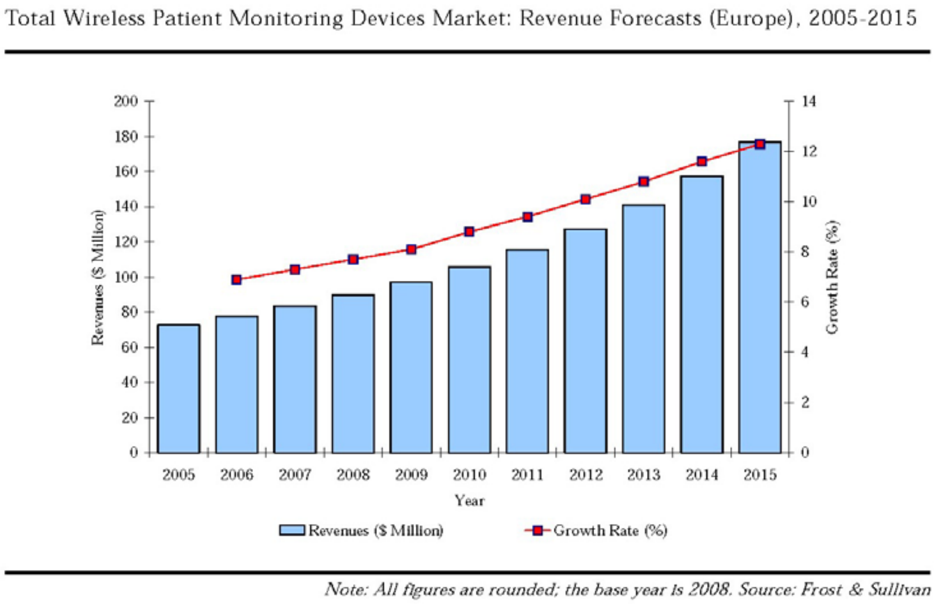


Figure 2: Total wireless patient monitoring devices market

6.2 Wireless patient monitoring in hospitals

When focusing on monitoring applications in the hospital, the trend is to significantly increase the number of monitored beds enabled by the introduction of wireless vital signs measurement devices on the general ward and medical surgery floor.

The number of staffed beds in Western European hospitals is 2,25 million (F&S Pulse Oximetry Report 2007, number of hospital beds in 2006).

Forecast calculations (source Philips Healthcare) show a 5 years average growth of 150 000 monitored beds/patients per year resulting from the introduction of wireless vital signs measurement devices. This forecast is based on an average of 45 % un-monitored beds (20 % of hospitals are teaching centres and have 75 % monitored beds, remainder of hospitals have 50 % monitored beds) and an adoption rate growing from 5 % in 2011 to 25 % in 2015. In addition to this, there will be a period (2011-2015) where wireless monitoring solutions will partly replace the already installed wired monitored solutions.

7 Technical information

The MBANS applications are quite diverse, ranging from low to high acuity monitoring services. Therefore, MBANS technical parameters may have a wide range. In this clause, typical low-power short-range radios are considered as technical examples. It is also noted that introducing necessary flexibility is critical to meet the requirements of future MBANS applications and to foster MBANS innovation.

7.1 Detailed technical description

Medical Body Area Networks, considered in the present document, are short-range low-power wireless networks, consisting of a plurality of tiny 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 temperature readings, pulse readings, blood glucose level readings, electrocardiogram readings, blood pressure level readings and readings relating to respiratory function, and forwarding the captured data wirelessly to a nearby hub device. The hub device 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. In special high acuity settings (e.g. in the ICU, ER and OR) medical actuators such as respirators or infusion pumps may belong to the MBANS and be controlled via commands transmitted by the hub device. The hub device also acts as a central controller to maintain the connections with all devices associated with its MBANS and is responsible for device association/de-association, channel selection and adaptive power control (APC). APC performance and requirements are to be confirmed by spectrum sharing compatibility studies. The link between a hub device and a sensor or actuator device will be bi-directional. It is expected that MBANSs will typically have a star topology while some other network topologies, such as Mesh, Hybrid and Tree, may also be adopted depending on specific application requirements.

Usually, MBANS devices are highly resource-constrained in terms of battery capacity, MCU capability and memory size. MBANS sensor devices typically have more stringent constraints than the hub device due to their small form-factor (to be wearable), low-cost and long battery life (especially for disposable sensor devices) requirements. 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 1bps/Hz and it is expected that MBANS solutions will have similar spectrum efficiency. Also to prolong battery life, MBANS devices are expected to operate at a limited duty cycle. Typically, the MBANS duty cycle (i.e. added for all devices that form a single MBANS) lies around or below 10 % for in-hospital applications and around 2 % or below for home-healthcare applications. It is expected that for future MBANS applications, the maximum MBANS duty cycle will not be more than 25 %. These estimated duty cycles already include the ARQ and other PHY/MAC layer overhead.

MBANS applications are likely to have very dynamic requirements in terms of communication range, data rates and link reliability. For in-hospital monitoring applications, the hub device is usually a bedside patient monitor locating inside patient's room or a portable patient monitor unit carried by patient. Typically, the required communication range is around 3 metres for the bedside patient monitor case (to cover a patient room) and 1 meter for the portable patient monitor case. For home healthcare monitoring applications, it is expected that a hub device will cover multiple rooms to increase patient mobility and reduce costs. Therefore, a longer communication range is preferred and usually 10 metres will be sufficient for most home healthcare applications. The required data rate may vary from bps to Mbps. For example, a high acuity ECG monitoring service in the ICU area may require > 100 Kbps application-level data rate while a SpO2 monitoring service for home healthcare chronic disease management applications may only require ~32 bps application-level data rate. It should be noted that future MBANS applications may require even higher data rates to provide more precise and demanding monitoring services. This will not have an impact on the maximum channel bandwidth and duty cycle. Considering the communication protocol overhead and low duty-cycle requirement, it is expected that the required MBANS wireless link raw data rate could be as high as 1 Mbps to ±5 Mbps. The link reliability requirement depends on the acuity level of MBANS applications. High acuity applications are more sensitive to data loss in a MBANS. It is expected that the application-level bit error rate less than 10^{-6} will meet the requirements of typical MBANS applications. Considering that automatic repeat request (ARQ), channel coding and other error correction methods are usually used in MBANSs, the maximum allowed raw bit error rate will be 10^{-4} for most MBANS applications.

MBANS devices may operate in ambient limited environments such as hospitals, small clinics, healthcare centres and assisted homes. It is expected that a contention-based protocol will be used for a MBANS device to share spectrum with other MBANS devices and other services. In some cases, as in emergency room area, it is required to support as many as 10 MBANSs to coexist with each other.

Clause 7.2 provides a more detailed description of the technical parameters of MBANSs.

7.2 Technical parameters and implications on spectrum

A spectrum portion of 40 MHz between 1 785 MHz and 2 500 MHz is required for MBANS operation. This requirement is based on multiple reasons discussed in greater detail in clause 8 and annex A.

7.2.1 Status of technical parameters

7.2.1.1 Current ITU and European Common Allocations

i) Current allocation of the candidate bands in the ITU-R Radio Regulations [i.4] is as follows.

Table 1: 1 710 MHz to 2 500 MHz ITU allocation

<table>
<tr><th colspan="3">Allocation to services</th></tr>
<tr><th>Region 1</th><th>Region 2</th><th>Region 3</th></tr>
<tr><td colspan="3">1 710 MHz to 1 930 MHz FIXED
MOBILE</td></tr>
<tr><td>2 300 MHz to 2 450 MHz
FIXED
MOBILE
Amateur
Radiolocation</td><td colspan="2">2 300 MHz to 2 450 MHz
FIXED
MOBILE
RADIOLOCATION
Amateur</td></tr>
<tr><td>2 450 MHz to 2 483,5 MHz
FIXED
MOBILE
Radiolocation</td><td colspan="2">2 450 MHz to 2 483,5 MHz
FIXED
MOBILE
RADIOLOCATION</td></tr>
<tr><td>2 483,5 MHz to 2 500 MHz
FIXED
MOBILE
MOBILE-SATELLITE
(space-to-Earth)
Radiolocation</td><td>2 483,5 MHz to 2 500 MHz
FIXED
MOBILE
MOBILE-SATELLITE
(space-to-Earth)
RADIOLOCATION
RADIODETERMINATION-
SATELLITE (space-to-Earth)</td><td>2 483,5 MHz to 2 500 MHz
FIXED
MOBILE
MOBILE-SATELLITE
(space-to-Earth)
RADIOLOCATION
Radiodetermination-
satellite (space-to-Earth)</td></tr>
</table>

ii) Current common allocation of the candidate bands in Europe is given in ERC Report 25 [i.3].

Table 2: 1 785 MHz to 1 800 MHz

Utilisation	ERC/ECC Documentation	European Standard
Mobile Applications (see note)	-	-
Radio microphones and assistive listening devices	ERC/REC 70-03 [i.9]	EN 300 422 [i.38] EN 301 840 [i.39] EN 300 454 [i.41]
Wireless audio applications	ERC/REC 70-03 [i.9]	EN 301 357 [i.40]
NOTE: This band is identified for IMT in the RRs, but within CEPT this band is not planned for the harmonised introduction of IMT.		

Table 3: 1 800 MHz to 1 805 MHz

Utilisation	ERC/ECC Documentation	European Standard
-	-	-
NOTE: This band is identified for IMT in the RRs, but within CEPT this band is not planned for the harmonised introduction of IMT.		

Table 4: 2 300 MHz to 2 400 MHz allocation in Europe

Utilisation	ERC/ECC Documentation	European Standard
Aeronautical Telemetry	ERC/REC 62-02 [i.5]	-
Amateur	-	EN 301 783 [i.7]
Mobile Applications	-	-
SAP/SAB	ERC/REC 25-10 [i.6]	EN 302 064 [i.8]
NOTE 1: ERC Recommendation 62-02 [i.5] recommends: *"1. that for future airborne telemetry applications the tuning range of equipment should primarily be in the frequency range 2300 - 2400 MHz;* *2. that the frequency band 2300 - 2330 MHz should primarily be used as a core band for airborne telemetry applications and that the band 2330 - 2400 MHz should be used as an extension band where required;* *3. that channels to be used in border areas be co-ordinated between the individual Administrations;"* NOTE 2: ERC Recommendation 25-10 [i.6] recommends: "*1. that CEPT administrations should assign frequencies for audio and video SAP/SAB links from the tuning ranges identified in annex 2":*		

Table 5: 2 400 MHz to 2 450 MHz

Utilisation	ERC/ECC Documentation	European Standard
Amateur	-	EN 301 783 [i.7]
Amateur satellite	-	EN 301 783 [i.7]
ISM	-	-
Non-specific SRDs	ERC/REC 70-03 [i.9]	EN 300 440 [i.35]
Radiodetermination applications	ERC/DEC/(01)08 [i.50] ERC/REC 70-03 [i.9]	EN 300 440 [i.35]
Railway applications	ERC/REC 70-03 [i.9]	EN 300 761 [i.37]
RFID	ERC/REC 70-03 [i.9]	EN 300 440 [i.35]
Wideband data transmission systems	ERC/DEC/(01)07 [i.49] ERC/REC 70-03 [i.9]	EN 300 328 [i.36]

Table 6: 2 450 MHz to 2 483,5 MHz

Utilisation	ERC/ECC Documentation	European Standard
ISM	-	-
Non-specific SRDs	ERC/REC 70-03 [i.9]	EN 300 440 [i.35]
Radiodetermination applications	ERC/DEC/(01)08 [i.50] ERC/REC 70-03 [i.9]	EN 300 440 [i.35]
Railway applications	ERC/REC 70-03 [i.9]	EN 300 761 [i.37]
RFID	ERC/REC 70-03 [i.9]	EN 300 440 [i.35]
Wideband data transmission systems	ERC/DEC/(01)07 [i.49] ERC/REC 70-03 [i.9]	EN 300 328 [i.36]

Table 7: 2 483,5 MHz to 2 500 MHz

Utilisation	ERC/ECC Documentation	European Standard
IMT satellite component	-	-
ISM	-	-
Mobile applications	-	-
Mobile satellite applications	ECC/DEC/(07)04 [i.42] ECC/DEC/(07)05 [i.43] ERC/DEC/(97)03 [i.44] ERC/DEC/(97)05 [i.45]	EN 301 441 [i.34] EN 301 473 [i.33]
SAP/SAB	ERC/REC 25-10 [i.6]	EN 302 064 [i.8]

Table 8: Recommended frequencies for SAP/SAB according to ERC/REC 25-10 [i.6]

	Recommended frequencies		**Technical parameters**
	Tuning ranges	**Preferred sub-bands**	
Cordless cameras	2 025 MHz to 2 110 MHz/ **2 200** MHz to **2 500** MHz 10,0 GHz to 10,60 GHz 21,2 GHz to 24,5 GHz 47,2 GHz to 50,2 GHz	10,3 GHz to 10,45 GHz 21,2 GHz to 21,4 GHz, 22,6 GHz to 23,0 GHz and 24,25 GHz to 24,5 GHz	ERC REP 38 [i.10]
Portable video links	2 025 MHz to 2 110 MHz/ **2 200** MHz to **2 500** MHz 2 500 MHz to 2 690 MHz (note 1) 10,0 GHz to 10,60 GHz	10,3 GHz to 10,45 GHz	ERC REP 38 [i.10]
Mobile video links (airborne and vehicular)	2 025 MHz to 2 110 MHz/ **2 200** MHz to **2 500** MHz 2 500 MHz to 2 690 MHz (note 1) 3 400 MHz to 3 600 MHz (note 2)		ERC REP 38 [i.10]
NOTE 1: The band 2 500 MHz to 2 690 MHz will not be available for video SAP/SAB links after the introduction of UMTS/IMT-2000 (see ECC/DEC/(02)06 [i.48]). NOTE 2: In countries where the band 3 400 MHz to 3 600 MHz is widely used for Fixed Wireless Access (FWA), availability of this band for mobile video SAP/SAB links may be restricted.			

7.2.1.2 Sharing and compatibility studies (if any) already available

The following compatibility study has already been conducted:

Analysis on compatibility of Low Power-Active Medical Implant (LP-AMI) applications within the frequency range 2 360 MHz to 3 400 MHz, in particular for the band 2 483,5 MHz to 2 500 MHz, with incumbent services (ECC Report 149 [i.11]).

Some of the information in such study could be used for further studies in the band, which may be required (e.g. amateur case).

7.2.1.3 Sharing and compatibility issues still to be considered

According to the ECA Table, following systems should be considered in any possible in-band compatibility scenario:

- Aeronautical telemetry
- Mobile applications
- Mobile satellite applications
- Radio microphones and assistive listening devices
- Wireless audio applications
- SAP/SAB
- Amateur radio
- Amateur satellite
- Radiodetermination applications
- Railway applications
- RFID
- Wideband data transmission systems
- IMT satellite component

In addition, LP-AMI should be considered in the 2 483,5 MHz to 2 500 MHz band for compatibility studies because of the very recent designation of the band to LP-AMI (see annex 12 of ERC/REC 70-03 [i.9]).

In addition, recently a compatibility study between BWS and existing services in the 2 300 MHz to 2 400 MHz band is being carried out by ECC PT SE7. This study is summarised in table 9.

Table 9: Compatibility study of BWS and existing services in the 2 300 MHz to 2 400 MHz band

Subject	Output	Start/Target dates	Remarks
Broadband Wireless Systems for 2 300 MHz to 2 400 MHz	ECC report covering : • compatibility studies between BWS and existing services in the band 2 300 MHz to 2 400 MHz and in adjacent spectrum bands; • development of appropriate measures to assist administrations in border coordination.	S: Sep 2010 T: Sept 2011	New task requested by WG FM. Coordination with ECC PT1 may be needed for BWS characteristics expected to be based on TDD in this band.

It is noted that SAP/SAB typically has e.i.r.p. up to 90 dBm while the average amateur station e.i.r.p. is of the order of 75 dBm to 80 dBm.

Deutscher Amateur Radio Club e.V (DARC) has made the following statement regarding MBANS operation in the 2 360 MHz to 2 400 MHz band: "Preliminary calculations show that for a MBANS receiver with the parameters defined in clause 7.2.3.1, an isolation of the order of 200 dB will be required from the average amateur station to give 2 dB degradation".

The Dutch Ministry of Economic Affairs Agriculture and Innovation is of the opinion that in any compatibility study, the actual amateur applications according to the IARU VHF handbook need to be considered.

ETSI MSG/ERM TFES has developed the Harmonised Standard EN 301 908 for IMT technologies covering the range of frequency bands identified for IMT technology. Of the four frequency bands proposed for MBANS devices, two of these are immediately adjacent to the IMT uplink (handset transmit) sub-bands. These adjacencies may require careful consideration from the compatibility perspective. See clause 7.2.1.3. The frequency band 2 300 MHz to 2 400 MHz is one band that has also been identified for IMT technology and some countries in Europe have formally made known their plans to issue national spectrum authorisations across this band for mobile broadband technologies including IMT. EN 301 908-19 [i.31] and EN 301 908-20 [i.32] covering Mobile WiMAX^{TM} IMT technology in the 2 300 MHz to 2 400 MHz band, which is identified as Mobile WiMAX^{TM} Band Class 1B has passed national vote and is awaiting publication by ETSI and citation in the OJEU. In addition, 3GPP technical specifications also address this frequency range for unpaired UTRA and E-UTRA as Band identifier e) and 40 respectively. The next release of EN 301 908 is expected to include these frequency ranges for the 3GPP technologies too.

ETSI ERM/MSG TFES has developed the Harmonised Standard EN 301 908 for IMT technologies and points out that: 1 785 MHz to 1 805 MHz is immediately adjacent to the widely deployed European 1 800 MHz band (where GSM, UMTS, LTE and WiMAX^{TM} are either deployed or possible in the near future). 2 483,5 MHz to 2 500 MHz is immediately adjacent to the IMT 2,6 GHz band which is currently being brought into service following recent spectrum authorisations to mobile operators. Most countries in Europe are planning to award this spectrum in the coming years. These adjacencies may require careful consideration from the compatibility perspective.

ETSI MSG/ERM TFES also points out that the frequency band 2 300 MHz to 2 400 MHz has also been identified for IMT technology and some countries in Europe have formally made known their plans to issue national spectrum authorisations across this band for mobile broadband technologies including IMT.

Ericsson objects against the request for designation in the frequency band 2 360 MHz to 2 400 MHz in the present document: System Reference document (SRdoc) on "Medical Body Area Network Systems (MBANSs) in the 1 785 MHz to 2 500 MHz range" for the following reasons:

1) the whole band 2 300 MHz to 2 400 MHz is identified to the International Mobile Telecommunication (IMT) in the treaty text of the International Telecommunication Union's Radio Regulations on a global basis;

2) IMT is currently being rolled out in several countries for mass-market mobile broadband systems, which make the band 2 360 MHz to 2 400 MHz less suitable for use of MBANSs in countries implementing IMT, including some countries in Europe, where MBANSs would be susceptible to interference from IMT devices worn and used by individual also wearing MBANS devices or by other individuals in the vicinity of such individual, and

3) a large number of systems, including integrated systems in IMT devices, are operating in the band above the frequency 2400 MHz where MBANSs operating in the band 2 360 MHz to 2 400 MHz would be susceptible to interference from systems integrated with IMT devices worn and used by individual also wearing MBANS devices or by other individuals in the vicinity.

Vodafone believes that the bands proposed in the present document are not suitable for MBANs, because of their proximity to high density mobile bands together with the following characteristics of MBANSs:

- Low power consumption and resulting poor receiver blocking performance.
- Expected frequency response of receiver front end filters at these frequencies.
- The QoS expectations for MBANS systems.

The Dutch Ministry of Economic Affairs Agriculture and Innovation has made the following statement:

In the note under table 14 of the present document, it is stated: "While the band 2300-2400 MHz has been identified by International Telecommunication Union (ITU) as one of the candidate bands for future IMT deployments, it is not a preferred band in Europe and only a handful of EU countries are even considering it for this purpose, with the majority preferring to use other bands like the 2 500 MHz and 3 400 MHz bands." The Dutch Ministry of Economic Affairs, Agriculture and Innovation supports the 2 360 MHz to 2 400 MHz band as one of the candidate bands for MBANS operation.

7.2.2 Transmitter parameters

7.2.2.1 Transmitter Output Power / Radiated Power

The maximum transmission power should be large enough to allow MBANS equipment to achieve sufficient communication ranges with required reliability. Based on the link budget analysis in annex A, the following maximum transmitter radiated power is proposed:

a) For MBANS transmitters operating indoor, in a sub-band reserved for use within healthcare facilities (defined as healthcare facility sub-band), the maximum e.i.r.p. over the emission bandwidth is not to exceed the lesser of 0 dBm or ($10 \log_{10}B$) dBm, where B is the 20 dB emission bandwidth in MHz.

b) For MBANS transmitters operating without location limitations (in location independent sub-band), the maximum e.i.r.p. over the emission bandwidth is not to exceed the lesser of 13 dBm or ($16+10 \log_{10}B$) dBm, where B is the 20 dB emission bandwidth in MHz.

The emission bandwidth dependency in the proposed radiated power limits aims at protecting other users, especially narrow band users, by ensuring that the radiated power spectral density never exceeds 1 mW/MHz (for the healthcare facility sub-band) and 40 mW/MHz (for the location independent sub-band). The radiated power limits are thus generally lower for narrowband MBANSs.

Low transmission power is critical for MBANS equipment to achieve long battery life and coexistence. Hence adaptive power control (APC) may be a beneficial mechanism for MBANSs, especially for MBANSs operating in the location independent sub-band. A dynamic APC range of 13 dB may be used.

7.2.2.1a Antenna Characteristics

Typical MBANSs may use either a dipole or omni-directional antenna. Body worn devices would likely use a small chip antenna in the dipole class. If a MBANS device were to use a higher antenna gain, it would be required to comply with the e.i.r.p. power limits proposed in the present document.

7.2.2.2 Operating Frequency

The preferred frequency band is 2 360 MHz to 2 400 MHz. Other suggested frequency bands of operation are 1 785 MHz to 1 805 MHz, 2 400 MHz to 2 483,5 MHz, and 2 483,5 MHz to 2 500 MHz. MBANS equipment may theoretically operate in any frequency within one of the former frequency bands, subject to the proposed regulations in clause 9.2 and provided that the out-of-band emissions are attenuated in accordance with the proposed regulations in clause 9.2. MBANS equipment will generally have a tuning range over the entire designated frequency band of operation to allow for intra- and inter-service compatibility (see clause A.1.2.2). Refer to clause 8.2 for the preliminary assessment. However, the accumulation of spectrum in the proposed frequency range beyond 40 MHz (e.g. up to 160 MHz) is not intended for MBANS operation.

A frequency stability tolerance of ±100 ppm is an acceptable limit for MBANS devices. However such frequency stability tolerance may only be applicable to MBANS devices that operate with a wide bandwidth (~5 MHz). MBANS devices operating with less bandwidth (e.g. 1 MHz to ±3 MHz) would typically operate with a lower frequency stability tolerance (e.g. ±20 ppm to ±50 ppm).

7.2.2.3 Bandwidth

Bandwidth 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 could be 3 MHz to 5 MHz. For low data-rate applications, the required bandwidth could be 1 MHz to 3 MHz. In general, the emission bandwidth will be no larger than 5 MHz. The justification for the data rates is given in clause A.1.2.2.

7.2.2.4 Unwanted emissions

MBANSs emission levels in the spurious domain would be compliant with ERC/REC 74-01 [i.12]. Other unwanted emission levels are identified through the transmitter spectrum emission mask specifications, as defined in clause 9.2.

Target levels for unwanted emissions in the spurious domain of -45 dBm e.i.r.p. in the 2 483,5 MHz to 2 500 MHz band and -60 dBm e.r.p. in the 401 MHz to 406 MHz band are to be aimed for. Further studies are required to determine the practicality of these levels.

7.2.3 Receiver parameters

7.2.3.1 Receiver Sensitivity

The MBANS receiver sensitivity depends on MBANS physical layer link design, such as coding and modulation schemes, and implementation parameters. Theoretically, the MBANS receiver sensitivity usually can be calculated as:

$$\text{Receiver Sensitivity [dBm]} = \text{Noise Power (N) [dBm]} + SNR_{Min} + \text{Implementation Loss (IL)} + \text{Receiver noise figure (NF)},$$

where the noise power N [dBm] = $10\log(K_B TB) + 30$, $K_B = 1{,}38 \times 10^{-23}$ J/K is the Boltzmann constant, T is the noise temperature (in K), B is the noise bandwidth (in Hz), and SNR_{Min} is the minimum Signal-to-Noise Ratio (SNR), expressed in dB, to achieve the required link performance.

For example, the following receiver sensitivity parameters (in left column of table 10) are used in the link budget analysis for the 1 Mbps uncoded FSK case (with modulation index 0,5) presented in annex A.

Table 10: Examples of receiver sensitivity parameters

Bandwidth B	1 MHz	5 MHz
Noise power N (T=290K)	-114 dBm	-107 dBm
NF	10 dB	10 dB
IL	6 dB	6 dB
SNR_{Min}	11,3 dB	11,3 dB
Receiver sensitivity	-86,7 dBm	-79,7 dBm
NOTE: The lower sensitivity for the 5 MHz emission bandwidth limit (in comparison with the 1 MHz case) may be compensated by means of channel coding/spectrum spreading. For an emission bandwidth above 1 MHz typical MBANS implementations may use such techniques to improve link performance.		

7.2.3.2 Receiver blocking

A target of -30 dBm e.i.r.p. with 3 dB blocking is aimed for.

7.2.3.3 Interference criteria

The MBANS receiver ability to operate under interference depends, amongst other aspects, on the utilized modulation, spectrum spreading, and channel coding techniques. It is expected that MBANS receivers be able to operate with a minimum carrier-to-interference ratio (C/I) of 15 dB or lower.

7.2.4 Channel access parameters

The proposed MBANSs will operate at limited duty cycle to reduce power consumption and avoid interference to other services. It is expected that a MBANS duty cycle for in-hospital use will be no larger than 25 %, and a typical value will be 10 %. For home healthcare MBANS application, it is expected that the transmission of continuous vital signs -such as raw ECG waves- will typically not be required. Hence a much lower MBANS duty cycle is expected; usually less than 2 %. Such duty cycle values are defined over a period of one hour, whereas the maximum duration of an uninterrupted transmission is proposed to be 10 seconds.

For the purpose of future compatibility studies the following expected MBANS density ranges are suggested:

- Inside healthcare facilities: 30 to 50 MBANSs per square kilometre.
- Outside the healthcare facilities (especially in patient homes): 5 to 20 MBANSs per square kilometre.

If Listen-Before-Talk (LBT) is used, duty cycle limitations would not apply. The LBT threshold may be calculated using the following formula: $(-140 + 10\text{Log}_{10}\text{B})$ dBm (e.g. -73 dBm for 5 MHz emission bandwidth) or -1 dB microvolt/metre per root Hertz. Where the radiated power is less than 0 dBm or 13 dBm as applicable, the LBT threshold may be raised by 1 dB for each dB the power is below the transmit power limit, up to a maximum of 20 dB. If LBT is used, channel occupancy is not to be checked before each acknowledgement message. Further details on LBT will be considered in the standard making process.

7.3 Information on relevant standard(s)

ETSI is expected to develop dedicated European Harmonised Standard(s) after the designation of the requested frequency band for MBANSs.

In accordance with note 2 of recommends 8 of ERC/REC 74-01 [i.12] given above, before developing a harmonised standard for MBANSs, the spurious emission limits should be reviewed by ETSI with a view as to whether the limits defined in ERC/REC 74-01 [i.12] are appropriate in the bands 401 MHz to 406 MHz, 1 785 MHz to 1 805 MHz, 2 360 MHz to 2 400 MHz, 2 400 MHz to 2 483,5 MHz, and 2 483,5 MHz to 2 500 MHz due to the expected close proximity between the ULP-AMI operating in the 401 MHz to 406 MHz, LP-AMI operating in the 2 483,5 MHz to 2 500 MHz band and MBANSs operating in a band within the 1 785 MHz to 2 500 MHz frequency range.

8 Radio spectrum request and justification

Medical Body Area Network Systems (MBANSs) will play a key role in serving the public interest by improving patient care, enabling electronic health records, reducing healthcare costs and furthering EU health strategy objectives of fostering good health in an ageing Europe by protecting citizens from health threats, and supporting dynamic health systems and new technologies [i.14].

In order to deliver health-critical patient monitoring, diagnosis and treatment services in hospitals and beyond hospital boundaries, a spectrum regulation for MBANSs is needed. As discussed in clause A.1.3 in greater detail, MBANSs require 40 MHz operational band, also to maximize opportunities for the compatibility with other services, to support the co-existence of multiple MBANSs, and to provide the spectrum needed for future innovation. More details can be found in annex A.

The band 2 360 MHz to 2 400 MHz was proposed initially, and the other three frequency bands (1 785 MHz to 1 805 MHz, 2 400 MHz to 2 483,5 MHz and 2 483,5 MHz to 2 500 MHz) were suggested for inclusion in the SRdoc during its development. A preliminary assessment of these frequency bands is given below.

8.1 Preliminary frequency band evaluation

The following aspects are considered important for the suitability and eligibility of a frequency band in the aforementioned frequency ranges:

- **Economic viability:** The manufacturing cost of MBANS sensors should be low enough to enable affordable MBANS equipment. Due to the expected MBANS market size, this will only be possible if existing mass-market low-power short-range radios are either directly used or leveraged via system design reuse. This (re)use will also significantly shorten time to market.
- **Quality of Service (QoS):** A high QoS will be possible if the frequency band is not intensively used by other users and if sufficient bandwidth is available.
- **Co-existence possibilities:** The usage conditions of other technologies in the frequency band and possibilities for spectrum use coordination.
- **Interregional harmonisation:** A strong harmonization in MBANS frequency designation is vital for the wide-scale deployment of these devices, ultimately leading to lower-cost and improved patient care.
- **Antenna size:** Small and efficient antennae are critical for small sensor devices that have limited space for antennae.

In the context of the previous aspects, the four candidate frequency bands in the 1 785 MHz to 2 500 MHz frequency range are preliminarily evaluated below with respect to their suitability for MBANSs.

8.1.1 1 785 MHz to 1 805 MHz

Economic viability: The vast majority of mass-market low-power short-range radios operate in the frequency bands used by ISM equipment. It is expected that the absence of such radios in this frequency range (or neighbouring frequency ranges) would hinder the development of inexpensive MBANS equipment and delay market introduction.

Quality of Service (QoS): CEPT developed two reports in response to EC Mandates, for the use of the UHF frequencies from 790 MHz to 862 MHz for mobile/fixed communication networks (MFCN). In 2010, ECC concluded that only the duplex gap of this range (821 MHz to 832 MHz) could be used by radio microphones. Due to this conclusion to close the majority of the 790 MHz to 862 MHz band for wireless microphones in Europe in the near future, wireless microphone manufacturers are already launching products in the 1 785 MHz to 1 805 MHz band. This migration process is expected to significantly increase the utilization of the band by radio microphones. Current utilisations include mobile applications, radio microphones and assistive listening devices and wireless audio applications [i.3]. 20 MHz of spectrum are available in this band.

Co-existence possibilities: This band is used by a number of applications. However, it is not intensively used yet. Radio microphones are one of the most possible users of this band in the near future due to the migration of radio microphones from 790 MHz to 862 MHz range to 1 785 MHz to 1 805 MHz.

Interregional harmonisation: No interregional harmonization can be currently foreseen in this band.

Antenna size: The frequency range of this band allows for the use of medium-sized antennas. Comparable antennas are, in this frequency range, around 33 % bigger than those used for 2,4 GHz wireless devices.

8.1.2 2 360 MHz to 2 400 MHz

Economic viability: The adjacency to the 2,4 GHz generic SRD band would allow exceedingly low power MBANS sensors to be manufactured inexpensively by leveraging existing low-power short-range radios developed for the 2.4 GHz generic SRD band, such as IEEE 802.15.4 radios [i.23].

Quality of Service (QoS): This band is currently sparsely utilized in Europe. Current utilisations include aeronautical telemetry on a national basis, amateur service, mobile applications and ancillary broadcast services [i.3]. 40 MHz of spectrum are available in this band.

Co-existence possibilities: Interference issues between MBANSs and aeronautical telemetry systems (ATS) in this band can be addressed by avoiding MBANS operation in the proximity of ATS installations, since there are very few of these that use the 2 360 MHz to 2 400 MHz spectrum. This proposal is already well developed in the US FCC discussions, and it is recognized that MBANSs can effectively meet the ITU-R Recommendation M.1459 for interference protection [i.13]. Adaptive frequency selection, listen-before-talk, adaptive power control and other features would enable opportunistic low-power, short-range MBANSs to achieve harmonized coexistence with ATS and amateur radios. It is possible that countries in Europe may issue spectrum authorisations for mobile broadband applications including IMT in the 2 300 MHz to 2 400 MHz band based on unpaired operation in contiguously aggregated 5 MHz blocks.

Interregional harmonisation: Proceedings are well underway in the US to allow MBANSs to operate in the 2 360 MHz to 2 400 MHz band. Industry and incumbent users did reach an agreement on how to share spectrum for MBANS applications. The FCC intends to publish final rules still in 2011.

Furthermore IEEE 802 is already working on MBANS standardization. In addition to ongoing activities in IEEE 802.15.6 [i.46] on body area networks, the IEEE 802.15.4j Task Group is developing the standard for MBANSs in the 2 360 MHz to 2 400 MHz band, by leveraging the existing IEEE 802.15.4 standard [i.23].

Antenna size: The frequency range of this band allows for the use of small antennas, similar or equal to those used in the neighbouring 2,4 GHz generic SRD band (e.g. in Bluetooth® and IEEE 802.15.4 devices).

8.1.3 2 400 MHz to 2 483,5 MHz (2,4 GHz generic SRD band)

Economic viability: The manufacture of inexpensive low power MBANS sensors would be possible by using existing low-power short-range radios developed for this band, such as IEEE 802.15.4 radios [i.23].

Quality of Service (QoS): This band is intensively used in hospitals and elsewhere. Current utilisations include amateur service, amateur satellite, ISM equipment, non-specific SRDs, radiodetermination applications, railway applications, RFID and wideband data transmission systems. 80 MHz of spectrum are available in this band.

Co-existence possibilities: This band is already intensively used by wireless networking devices in hospital, such as WiFi devices. The higher TX-power, greater emission bandwidth and lower QoS requirements of such non-medical devices put MBANS devices in a clearly unfavourable position with respect to co-existence. Hence, despite the significant amount of available spectrum, the growth of lower TX-power (0 dBm) MBANS devices would be jeopardized in this band.

Interregional harmonisation: This band is effectively harmonised internationally for generic SRD. For MBANSs no interregional harmonisation can be currently foreseen in this band.

Antenna size: The frequency range of this band allows for the use of small antennas, for example those used in Bluetooth® and IEEE 802.15.4 devices.

8.1.4 2 483,5 MHz to 2 500 MHz

Economic viability: Equally to the 2 360 MHz to 2 400 MHz band, this frequency band is immediately adjacent to the 2,4 GHz generic SRD band. Likewise this would allow exceedingly low power MBANS sensors to be manufactured inexpensively by leveraging existing low-power short-range radios developed for the 2,4 GHz generic SRD band.

Quality of Service (QoS): Current utilisations include IMT satellite component, ISM, mobile applications, mobile satellite applications and ancillary broadcast services [i.3]. The Mobile Satellite Service (MSS) applications are mainly by Globalstar and Iridium satellite systems and serves to approximately 500 000 subscribers worldwide. The mobile service is the recent implementation of Complementary Ground Component (CGC) of the satellite networks whereas terrestrial base stations, operating within the same frequency band, would be installed in order to improve the coverage of MSS signals. SAP/SAB systems are also implemented in a number of European countries in the same band. Also, just above the 2 500 MHz, IMT systems operated within the band 2 500 MHz to 2 690 MHz. Finally, very recently, this band was designated by the CEPT for use by low power-active medical implants (LP-AMI) which is expected to be used intensively in the health care facilities. 16,5 MHz of spectrum are available in this band.

Co-existence possibilities: This band has been designated by the ECC for LP-AMI usage. A specific regulation has been introduced into the annex 12 of ERC/REC 70-03 [i.9] in this context. The co-location of MBANS and LP-AMI devices within a few centimetres from each other (carried by the same body) suggest potential co-existence problems, especially for the highly sensitive LP-AMI applications.

Interregional harmonisation: No interregional harmonization can be currently foreseen in this band.

Antenna size: The frequency range of this band allows for the use of small antennas, similar or equal to those used in the neighbouring 2,4 GHz generic SRD band (e.g. in Bluetooth® and IEEE 802.15.4 devices).

8.2 Summary of the preliminary assessment of the frequency bands

On the basis of the considerations given above, the following summary can be drawn:

- 1 785 MHz to 1 805 MHz band is only 20 MHz and does not provide a sufficient amount of spectrum to accommodate the requirement for MBANS. Also, it cannot be combined with another candidate band due to the distance to the other bands in frequency, which makes it difficult to use existing radio technology.
- 2 360 MHz to 2 400 MHz band can accommodate the requirement for MBANS with reasonable cost. Possibility of interregional harmonisation of the band for MBANS use makes this band more preferable in comparison with the other candidate bands.
- 2 400 MHz to 2 483,5 MHz band is designated for ISM and allocated to other services, and is intensively used by many applications including some "in-hospital" applications, such as Wi-Fi devices which makes it very difficult for use by MBANS.
- 2 483,5 MHz to 2 500 MHz band is only 16,5 MHz and does not provide a sufficient amount of spectrum to accommodate the operational requirements for MBANS. The co-location of MBANS and LP-AMI devices within a few centimetres of each other suggests potential co-existence problems, which makes MBANS unlikely to be used in the presence of LP-AMI.

9 Regulations

9.1 Current regulations

9.1.1 ITU-R Radio Regulations

The ITU-R Radio Regulations [i.4] allocate the candidate bands as reported in the present clause.

Table 11: Allocation of 1 700 MHz to 2 500 MHz band according to ITU-R Radio Regulations [i.4]

Allocation to services		
Region 1	**Region 2**	**Region 3**
1 710 MHz to 1 930 MHz FIXED MOBILE 5.384A 5.387		
2 300 MHz to 2 450 MHz FIXED MOBILE 5.384A Amateur Radiolocation 5.150 5.282	**2 300 MHz to2 450 MHz** FIXED MOBILE 5.384A RADIOLOCATION Amateur 5.150 5.282	
2 450 MHz to 2 483,5 MHz FIXED MOBILE Radiolocation 5.150 5.397	**2 450 MHz to 2 483,5 MHz** FIXED MOBILE RADIOLOCATION 5.150	
2 483,5 MHz to 2 500 MHz FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A Radiolocation 5.150 5.371 5.397 5.398 5.402	**2 483,5 MHz to 2 500 MHz** FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A RADIOLOCATION RADIODETERMINATION-SATELLITE (space-to-Earth) 5.398 5.150 5.402	**2 483,5 MHz to 2 500 MHz** FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A RADIOLOCATION Radiodetermination-satellite (space-to-Earth) 5.398 5.150 5.402

NOTE: Only the relevant footnotes are included in the table.

Footnotes:

5.150 The following bands:

13 553 kHz to 13 567 kHz	(centre frequency 13 560 kHz),
26 957 kHz to 27 283 kHz	(centre frequency 27 120 kHz),
40,66 MHz to 40,70 MHz	(centre frequency 40,68 MHz),
902 MHz to 928 MHz	in Region 2 (centre frequency 915 MHz),
2 400 MHz to 2 500 MHz	(centre frequency 2 450 MHz),
5 725 MHz to 5 875 MHz	(centre frequency 5 800 MHz), and
24 GHz to 24,25 GHz	(centre frequency 24,125 GHz)

are also designated for industrial, scientific and medical (ISM) applications. Radiocommunication services operating within these bands must accept harmful interference which may be caused by these applications. ISM equipment operating in these bands is subject to the provisions of No. 15.13.

5.384A The bands, or portions of the bands, 1 710 MHz to 1 885 MHz, 2 300 MHz to 2 400 MHz and 2 500 MHz to 2 690 MHz, are identified for use by administrations wishing to implement International Mobile Telecommunications (IMT) in accordance with Resolution 223 (Rev.WRC-07). This identification does not preclude the use of these bands by any application of the services to which they are allocated and does not establish priority in the Radio Regulations (WRC-07).

5.282 In the bands 435 MHz to 438 MHz, 1 260 MHz to 1 270 MHz, 2 400 MHz to 2 450 MHz, 3 400 MHz to 3 410 MHz (in Regions 2 and 3 only) and 5 650 MHz to 5 670 MHz, the amateur-satellite service may operate subject to not causing harmful interference to other services operating in accordance with the table (see No. **5.43**). Administrations authorizing such use shall ensure that any harmful interference caused by emissions from a station in the amateur-satellite service is immediately eliminated in accordance with the provisions of No. **25.11**. The use of the bands 1 260 MHz to 1 270 MHz and 5 650 MHz to 5 670 MHz by the amateur-satellite service is limited to the Earth-to-space direction.

5.351A For the use of the bands 1 518 MHz to 1 544 MHz, 1 545 MHz to 1 559 MHz, 1 610 MHz to 1 645,5 MHz, 1 646,5 MHz to 1 660,5 MHz, 1 668 MHz to 1 675 MHz, 1 980 MHz to 2 010 MHz, 2 170 MHz to 2 200 MHz, 2 483,5 MHz to 2 520 MHz and 2 670 MHz to 2 690 MHz by the mobile-satellite service, see Resolutions 212 (Rev.WRC-07) and 225 (Rev.WRC-07).

5.371 *Additional allocation:* in Region 1, the bands 1 610 MHz to 1 626,5 MHz (Earth-to-space) and 2 483,5 MHz to 2 500 MHz (space-to-Earth) are also allocated to the radiodetermination-satellite service on a secondary basis, subject to agreement obtained under No. **9.21**.

5.387 *Additional allocation:* in Belarus, Georgia, Kazakhstan, Mongolia, Kyrgyzstan, Slovakia, Romania, Tajikistan and Turkmenistan, the band 1 770 MHz to 1 790 MHz is also allocated to the meteorological-satellite service on a primary basis, subject to agreement obtained under No. **9.2**1 (WRC-07).

5.394 In the United States, the use of the band 2 300 MHz to 2 390 MHz by the aeronautical mobile service for telemetry has priority over other uses by the mobile services. In Canada, the use of the band 2 360 MHz to 2 400 MHz by the aeronautical mobile service for telemetry has priority over other uses by the mobile services (WRC-07).

5.397 *Different category of service:* in France, the band 2 450 MHz to 2 500 MHz is allocated on a primary basis to the radiolocation service (see No. **5.33**). Such use is subject to agreement with administrations having services operating or planned to operate in accordance with the Table of Frequency Allocations which may be affected.

5.398 In respect of the radiodetermination-satellite service in the band 2 483,5 MHz to 2 500 MHz, the provisions of No. **4.10** do not apply.

5.402 The use of the band 2 483,5 MHz to 2 500 MHz by the mobile-satellite and the radiodetermination-satellite services is subject to the coordination under No. **9.11A**. Administrations are urged to take all practicable steps to prevent harmful interference to the radio astronomy service from emissions in the 2 483,5 MHz to 2 500 MHz band, especially those caused by second-harmonic radiation that would fall into the 4 990 MHz to 5 000 MHz band allocated to the radio astronomy service worldwide.

9.1.2 European Common Allocation Table

The European Common Allocation Table (ERC Report 25) [i.3] gives the utilisation of candidate bands in Europe.

Table 12: Utilisation of the 1 785 MHz to 1 800 MHz band in Europe

RR Region 1 Allocation and RR footnotes applicable to CEPT	European Common Allocation	Major utilisation	European footnotes	ECC/ERC document	Standard	Notes
FIXED	FIXED	Mobile applications	EU2 EU15	-		This band is identified for IMT in the RRs, but within CEPT this band is not planned for the harmonised introduction of IMT
MOBILE	MOBILE	Radio microphones and assistive listening devices		ERC/REC 70-03 [i.9]	EN 300 422 [i.38] EN 301 840 [i.39] EN 300 454 [i.41]	
		Wireless audio applications		ERC/REC 70-03 [i.9]	EN 301 357 [i.40]	Within the band 1 795 MHz to 1 800 MHz

Table 13: Utilisation of the 1 800 MHz to 1 805 MHz band in Europe

RR Region 1 Allocation and RR footnotes applicable to CEPT	European Common Allocation	Major utilisation	European footnotes	ECC/ERC document	Standard	Notes
FIXED	Fixed	-	-	-	-	This band is identified for IMT in the RRs, but within CEPT this band is not planned for the harmonised introduction of IMT
MOBILE	MOBILE	-	-	-	-	

Table 14: Utilisation of the 2 300 MHz to 2 400 MHz band in Europe

RR Region 1 Allocation and RR footnotes applicable to CEPT	European Common Allocation	Major utilisation	European footnotes	ECC/ERC document	Standard	Notes
FIXED	FIXED	Aeronautical telemetry		ERC/REC 62-02 [i.5]		Parts of the band are used for aeronautical telemetry on a national basis
MOBILE	MOBILE	**Amateur**			EN 301 783 [i.7]	
Amateur	Amateur	**Mobile applications**				
Radiolocation	Radiolocation	**SAP/SAB**				
5.395	EU2 EU15			ERC/REC 25-10 [i.6]	EN 302 064 [i.8]	
NOTE: In Europe, the allocation of FIXED and MOBILE is on a primary basis, while the allocation of Amateur and Radiolocation is on a secondary basis. Major utilisations identified for the 2 360 MHz to 2 400 MHz band include aeronautical telemetry on a national basis, amateur use, mobile applications and ancillary broadcast services [i.3]. While the band 2 300 MHz to 2 400 MHz has been identified by International Telecommunication Union (ITU) as one of the candidate bands for future IMT deployments, it is not a preferred band in Europe and only a handful of EU countries are even considering it for this purpose, with the majority preferring to use other bands like the 2 500 MHz and 3 400 MHz bands. Examination of the implementation status of relevant ERC/ECC Recommendations shows no IMT services are currently deployed in the 2 360 MHz to 2 400 MHz band. In the US, the Federal Communications Commission (FCC) has been evaluating the use of the 2 360 MHz to 2 400 MHz frequency band for MBANSs on a secondary basis. The FCC issued a Notice of Proposed Rulemaking (NPRM) for MBANS regulation in 2009 [i.2] and interested parties are currently making ex parte presentations to the FCC, following which the FCC will draft an order for public comments. The FCC MBANS NPRM record reflects broad support for the allocation of a dedicated spectrum for MBANS devices and services. In January 2010 GE Healthcare, Philips Healthcare, and AFTRCC (Aerospace and Flight Test Radio Coordinating Council) presented the FCC with a joint MBANS rules draft proposal [i.24].						

Table 15: Utilisation of the 2 450 MHz to 2 483,5 MHz band in Europe

RR Region 1 Allocation and RR footnotes applicable to CEPT	European Common Allocation	Major utilisation	European footnotes	ECC/ERC document	Standard	Notes
FIXED	FIXED	ISM	EU2	-	-	
MOBILE	MOBILE	Non-specific SRDs		ERC/REC 70-03 [i.9]	EN 300 440 [i.35]	
Radio location		Radiodetermination applications		ERC/DEC/(01)08 [i.50] ERC/REC 70-03 [i.9]	EN 300 440 [i.35]	
		Railway applications		ERC/REC 70-03 [i.9]	EN 300 761 [i.37]	Within the band 2 446 MHz to 2 454 MHz for AVI applications
		RFID		ERC/REC 70-03 [i.9]	EN 300 440 [i.35]	Within the band 2 446 MHz to 2 454 MHz
		Wideband data transmission systems		ERC/DEC/(01)07 [i.49] ERC/REC 70-03 [i.9]	EN 300 328 [i.36]	

Table 16: Utilisation of the 2 483,5 MHz to 2 500 MHz band in Europe

RR Region 1 Allocation and RR footnotes applicable to CEPT	European Common Allocation	Major utilisation	European footnotes	ECC/ERC document	Standard	Notes
FIXED	FIXED	IMT satellite component		-	-	
MOBILE MOBILE-SATELLITE (S/E)	MOBILE MOBILE-SATELLITE (S/E)	ISM		-	-	
		Mobile applications		-	-	
		Mobile satellite applications		ECC/DEC/(07)04 [i.42] ECC/DEC/(07)05 [i.43] ERC/DEC/(97)03 [i.44] ERC/DEC/(97)05 [i.45]	EN 301 441 [i.34] EN 301 473 [i.33]	
		SAP/SAB		ERC/REC 25-10 [i.6]	EN 302 064 [i.8]	

9.2 Proposed regulation and justification

ECC is requested to designate 40 MHz of frequency spectrum for MBANS operations on an underlay use basis. The proposed specifications of MBANS operation are as follows:

- ***Eligibility***

  Operation of MBANS devices is permitted under a license-exempt regulation. Duly authorized healthcare professionals are permitted to operate MBANS transmitters. In addition, any person is authorized to operate MBANS transmitters if prescribed by a duly authorized healthcare professional. Manufacturers of MBANS transmitters and their representatives are authorized to operate MBANS transmitters for the purpose of developing, testing and demonstrating such equipment.

- ***Permissible communications***

  MBANS transmitters prescribed by duly authorized healthcare professionals may transmit only information used for monitoring, diagnosing or treatment of patients. All voice communications between devices, including digitized voice, are prohibited.

- ***Frequencies & Authorized locations***

  a) Healthcare facility sub-band: Use of MBANS devices is restricted to indoor operation within a healthcare facility. A MBANS device capable of operating in the healthcare facility sub-band employs a mechanism which ensures that operation in such band is suppressed outside a healthcare facility.

  b) Location independent sub-band: MBANS operation is authorized indoor as well as outdoor.

  It is proposed that the bigger portion (75 %) of the required MBANS operational band be used inside healthcare facilities only (healthcare facility sub-band) and the remaining portion (25 %) be used independently from the MBANS location (location independent sub-band).

  As discussed in clause 8, it should be noted that the 1 785 MHz to 1 805 MHz and 2 483,5 MHz to 2 500 MHz bands cannot accommodate the operational bandwidth needs of MBANSs.

- ***Emission types***

  A MBANS transmitter may emit any emission type appropriate for data communications in MBANSs. MBANS transmissions follow a contention-based protocol and/or duty cycle still to be determined by compatibility studies.

- ***Emission bandwidth***

  a) The maximum authorized emission bandwidth is 5 MHz. A justification for the proposed emission bandwidth is given in clause A.1.2.2.

  b) The emission bandwidth is determined by measuring the width of the modulated emission between the frequencies furthest above and furthest below the frequency of maximum power where the emission power drops 20 dB with respect to its maximum level.

  Information on Specific Absorption Rate (SAR) exposure levels generated by MBANS applications is given in clause A.2.

- ***Maximum radiated power***

  a) For MBANS transmitters operating within the healthcare facility sub-band, the maximum e.i.r.p. over the emission bandwidth is not to exceed the lesser of 0 dBm or (10 $\log_{10}$B) dBm, where B is the 20 dB emission bandwidth in MHz.

  b) For MBANS transmitters operating within the location independent sub-band, the maximum e.i.r.p. over the emission bandwidth is not to exceed the lesser of 13 dBm or (16+10 $\log_{10}$B) dBm, where B is the 20 dB emission bandwidth in MHz.

  c) APC may be used by MBANS transmitters, especially by those operating in the location independent sub-band. A dynamic APC range of 13 dB may be used.

- ***Unwanted Radiation***

Table 17 gives the emission limits in the spurious domain, as defined in ERC/REC 74-01 [i.12].

Table 17: Emission limits in the spurious domain

Frequency / State	47 MHz to 74 MHz 87,5 MHz to 118 MHz 174 MHz to 230 MHz 470 MHz to 862 MHz	Other frequencies below 1 000 MHz	Frequencies above 1 000 MHz
Operating	-54 dBm	-36 dBm	-30 dBm
Standby	-57 dBm	-57 dBm	-47 dBm

Note 2 of recommends 8 of ERC/REC 74-01 [i.12] states that "where either CEPT or ETSI consider the limits defined in this Recommendation are inappropriate for a particular standard an agreement on alternative limits should be reached by application of the MoU between ETSI and CEPT".

The detailed justification for the proposed regulation is presented in annex A.

Annex A: Detailed technical information

A.1 Technical parameters and justifications for spectrum

A.1.1 Maximum Radiated Power

A.1.1.1 Proposed Maximum Radiated Power

The following radiated power limits are proposed to meet the requirements of both in-hospital and in-home MBANS applications.

a) For MBANS transmitters operating within the healthcare facility sub-band, the maximum e.i.r.p. over the emission bandwidth is not to exceed the lesser of 0 dBm or (10 $\log_{10}$B) dBm, where B is the 20 dB emission bandwidth in MHz.

b) For MBANS transmitters operating within the location independent sub-band, the maximum e.i.r.p. over the emission bandwidth is not to exceed the lesser of 13 dBm or (16+10 $\log_{10}$B) dBm, where B is the 20 dB emission bandwidth in MHz.

The proposed radiated power limits will enable Medical Body Area Network Systems to bear health-critical services with currently-available commercial technologies while minimizing the potential for interference to other co-channel users. The MBANS bandwidth dependency in the proposed radiated power limits aims at protecting other users, especially narrow band users, by ensuring that the radiated power spectrum density never exceeds 1 mW/MHz (for the healthcare facility sub-band) and 40 mW/MHz (for the location independent sub-band). The generic e.i.r.p. limits of 0 dBm and 13 dBm are thus lower for narrowband MBANSs.

A.1.1.2 Link Budget Analysis

Link budget analysis is presented to demonstrate that the proposed maximum radiated power limits are sufficient to meet the performance requirements of typical short-range MBANS applications.

A.1.1.2.1 MBANS Radio Parameters

For MBANS applications with all levels of acuity, an application-level bit error rate (BER) no larger than 10^{-6} is acceptable to guarantee QoS. Considering possible retransmission techniques that could be adopted to improve application-level BER performance, the minimum physical-layer BER of 10^{-4} is used in the analysis. This assumption is reasonable and with such physical-layer BER performance requirement and retransmission techniques, it is feasible to achieve the required QoS of MBANS applications.

Within the 1785-2500 MHz frequency range, no commercially available low-power short-range radios have been identified to use other bands than the 2,4 GHz generic SRD band. Those mature low-power short-range radios from the 2,4 GHz generic SRD band may be re-tuned to other frequencies in the 1785-2500 MHz range for MBANS applications. Such re-tuning is expected to be cost effective for the 2360-2400 MHz and 2483,5-2500 MHz bands. Therefore, several typical low-power short-range radios from 2,4 GHz generic SRD band, including:

1) IEEE 802.15.4 DSSS + O-QPSK with a 20 dB bandwidth of 2,6 MHz and 250 Kbps data rate;

2) O-QPSK with a 20 dB bandwidth of 2,6 MHz and 2 Mbps data rate; and

3) FSK modulation with modulation index of 0,5, 1 MHz bandwidth and 1 Mbps data rate.

are considered as examples in the link budget analysis. The BER performance curves of these radios are shown in figure A.1. The simulated channel mode is the additive white Gaussian noise (AWGN) channel.

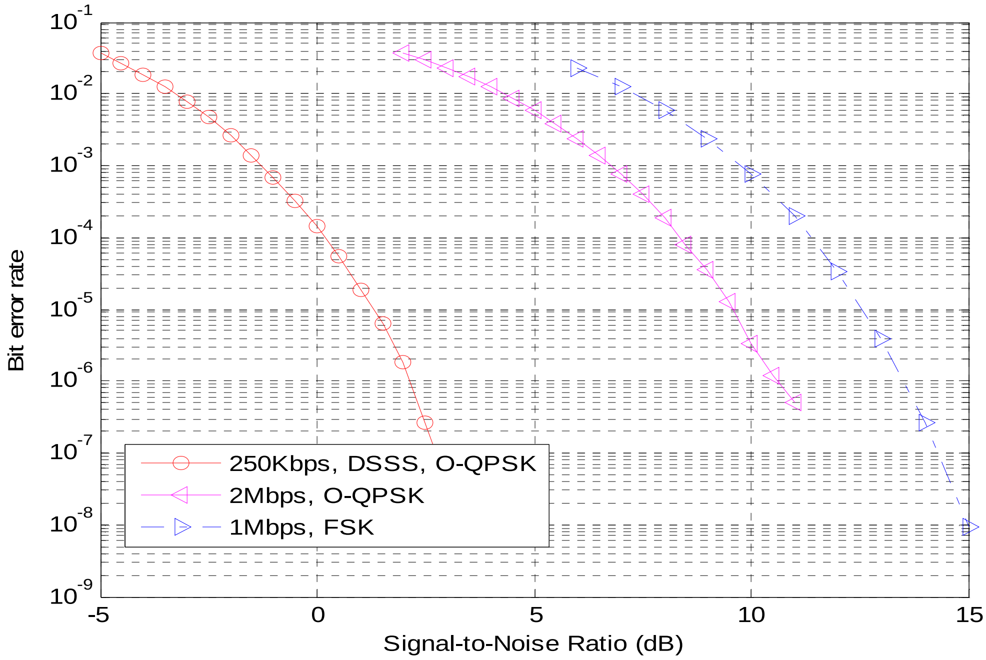


Figure A.1: BER performance of several mature modulation schemes

A.1.1.2.2 Link Budget Analysis for In-hospital MBANS Applications

One typical in-hospital MBANS usage is for communications between an on-body MBANS sensor device to an external MBANS hub device (e.g. bedside patient monitor) within a same room, as shown in figure A.2. In this case, the required communication range of the MBANS radio link is 3 meters, which is to cover a typical patient room.

Table A.1 summarizes the link budget analysis results with the following assumptions: AWGN channel model with free-space path loss, 3 meter communication range, 0 dBi TX and RX antenna gains, central frequency of 2 500 MHz (worst case), 10 dB noise figure and 6 dB implementation loss.

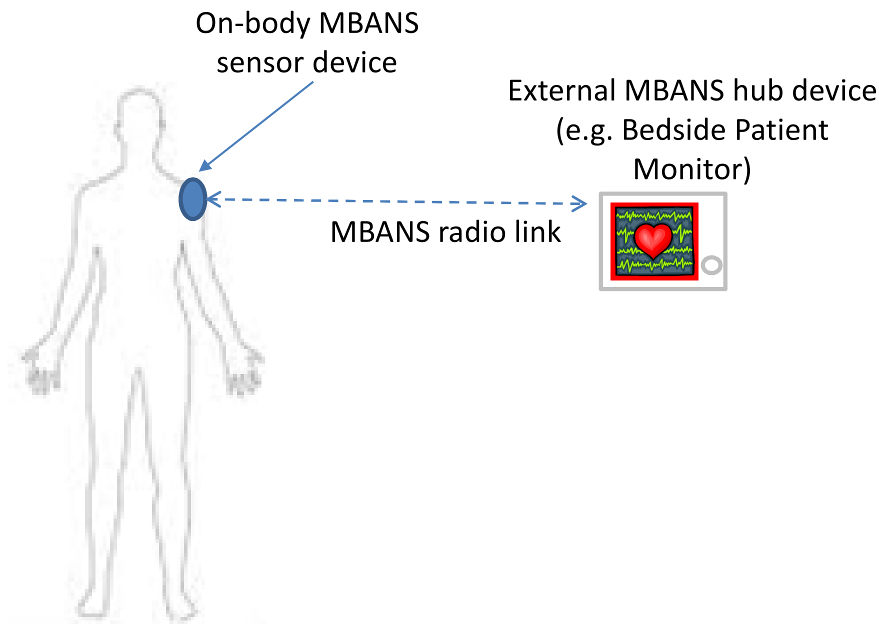


Figure A.2: In-hospital MBANS with external hub device

Table A.1: Link budget analysis for MBANS links between on-body sensors and external hub devices

Parameter	DSSS O-QPSK	O-QPSK	FSK
Information data rate (R_b) [Mbps]	0.25	2	1
Average TX power (P_T)[dBm]	0	0	0
TX antenna gain (G_T)[dBi]	0	0	0
Center frequency (f_c) [MHz]	2500	2500	2500
Path loss at 3 meter, $L_1 = 20\log_{10}\{(4\pi f_c d/(3\times 10^8))\}[dB]$	49.9	49.9	49.9
RX antenna gain (G_R) [dBi]	0	0	0
RX power ($P_R = P_T + G_T + G_R - L_1$) at $3m$	-49.9	-49.9	-49.9
Average noise power ($N = -174 + 10 * log_{10}(BW)$) [dBm]	-109.9	-109.9	-114
RX noise figure referred to the antenna terminal (N_F) [dB]	10	10	10
Total noise power ($P_N = N + N_F$) [dBm]	-99.9	-99.9	-104
Required Minimum SNR (S) [dB]	0.2	8.4	11.4
Implementation loss (I) [dB]	6	6	6
Link Margin ($M = P_R - P_N - S - I$), $d = 3$m [dB]	43.8	35.6	36.7

In all the three cases, more than 35 dB link margins are achieved. These high link margins can be used to counteract the fading effects introduced by the presence of the human body and imperfect antenna orientation/matching. In reality, proximity to the human body introduces shadowing of signals from the opposite side of body-worn MBANS antenna and also influences the tuning and radiated efficiency of the MBANS antenna. For example, the channel fading statistics of the 2360-2483,5 MHz frequency range were calculated in [i.15] using the CM4 (on-body to external device) channel models developed by IEEE 802.15.6 [i.46]. It was shown that the 99 %-tile fade depth at 3 meters is 19 dB. The link budgets after considering this 99 % fade depth are summarized in table A.2.

Table A.2: Realistic link margins of MBANS links between on-body sensors to external hub devices

Parameter	DSSS, O-QPSK	O-QPSK	FSK
AWGN link margin	43,8 dB	35,6 dB	36,7 dB
99 % fade depth at 3 m, CM4	19 dB	19 dB	19 dB
Realistic Link Margin	25,8 dB	16,6 dB	17,7 dB

After considering the 19 dB 99 %-tile fade, the achieved link margins with 0 dBm transmission power are 25,8 dB for the IEEE 802.15.4 solution, and more than 16 dB for the O-QPSK and FSK cases. The high link margins enable MBANS radios to tolerate moderate interference.

Moreover, high link margins imply that the proposed 0 dBm transmission power limit is sufficient to support possibly higher data rate services in future MBANS applications which may require higher SNR.

Another typical in-hospital MBANS usage is for on-body communications (e.g. communications between an on-body sensor device and an on-body hub device), which is shown in figure A.3.

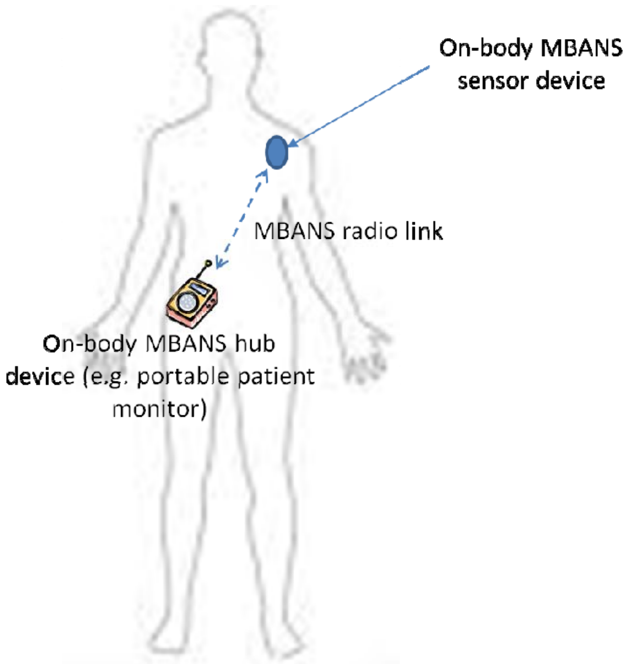


Figure A.3: In-hospital MBANS with on-body hub device

In this case, a typical communication range of the MBANS radio link is 1 meter. To model realistic on-body channels, the two CM3 (on-body) channel models, which were developed in the IEEE 802.15.6 [i.46] based on extensive measurements conducted by different organizations [i.16], are adopted.

The first model was proposed by NICT (Japan) and the pathloss can be calculated as:

$$PL(d)[dB] = a * \log_{10}(d) + b + N$$

where a = 6,6 dB , b = 36,1 dB, N is a normally distributed variable with zero mean and standard deviation of 3,8 dB and d is the TX-RX distance in mm.

The second model was proposed by IMEC (Netherlands) and the pathloss formula is:

$$PL(d)[dB] = -10 * \log_{10}(P_0 e^{-m_0 d} + P_1) + N$$

where P_0 = -25,8 dB, m_0 = 2,0 dB/cm, P_1 = -71,3 dB, N is a normally distributed variable with zero mean and standard deviation of 3,6 dB and d is the TX-RX distance in cm.

With a TX-RX distance of 1 meter, the pathloss (in dB) generated with the NICT model is a normally distributed random variable with mean of 55,9 dB and standard deviation of 3,8 dB (i.e. with 99 % probability an on-body channel with a TX-RX distance of 1 meter has a pathloss value lower than 55,9 + 2,3*3,8 = 64,6 dB) while the pathloss (in dB) generated with the IMEC model is a normally distributed random variable with mean of 71,3 dB and standard deviation of 3,6 dB (that i.e. with 99 % probability an on-body channel with a TX-RX distance of 1 meter has a pathloss value lower than 71,27 + 2,3*3,6 = 79,6 dB). In the analysis, 79,6 dB is used as pathloss. It is worth noting that 79,6 dB is a conservative choice that covers most of the channel measurement results in the literature, for example see [i.17].

Table A.3: Link Budget Analysis for on-body MBANS communications

Parameter	DSSS O-QPSK	O-QPSK	FSK
Information data rate (R_b) [Mbps]	0.25	2	1
Average TX power (P_T)[dBm]	0	0	0
TX antenna gain (G_T)[dBi]	0	0	0
Center frequency (f_c) [MHz]	2500	2500	2500
Path loss with $TX - RX = 1$ meter [dB]	79.6	79.6	79.6
RX antenna gain (G_R) [dBi]	0	0	0
RX power ($P_R = P_T + G_T + G_R - L_1$) at $1m$	-79.6	-79.6	-79.6
Average noise power ($N = -174 + 10 * log_{10}(BW)$) [dBm]	-109.9	-109.9	-114
RX noise figure referred to the antenna terminal (N_F) [dB]	10	10	10
Total noise power ($P_N = N + N_F$) [dBm]	-99.9	-99.9	-104
Required Minimum SNR (S) [dB]	0.2	8.4	11.4
Implementation loss (I) [dB]	6	6	6
Link Margin ($M = P_R - P_N - S - I$), $d = 3$m [dB]	14.1	5.9	7

Table A.3 shows that a 0 dBm transmission power can provide a 14,1 dB link margin in the DSSS O-QPSK case, 5,9 dB margin for O-QPSK, and 7 dB margin for FSK cases for on-body MBANS communications.

Based on the above analysis, it is concluded that 0 dBm transmission power limit is sufficient to provide the required link performance for short-range MBANS applications. This is also confirmed by the receiver sensitivity parameters of commercially available 2,4 GHz transceivers from different vendors. With a 0 dBm transmission power and a path loss of 79,6 dB (the higher of CM3 and CM4 channels), the receiver sensitivity of a MBANS transceiver should be -79,6 dBm or better. Below we list the sensitivity parameters of some commercial 2,4 GHz transceivers. It shows that most of them can achieve such sensitivity requirements. As discussed in clause A.1.1.2.1, mature low-power short-range radios from the 2,4 GHz generic SRD band may be re-tuned to other frequencies bands in the 1 785 MHz to 2 500 MHz frequency range. In such case, it is expected that the receiver sensitivity performance would not change significantly. Therefore, the -79,6 dBm sensitivity requirement should be achievable with current technologies in the 1 785 MHz to 2 500 MHz range.

Table A.4: Example of generic SRD radios that can be leveraged for MBANSs

Transceiver chipsets	Technical Parameters	Receiver sensitivity
Texas Instruments/Chipcon CC2400 [i.26]	1 Mbps, 1 MHz channel BW, FSK 250 kbps, 1 MHz channel BW, FSK 10 kbps, 500 kHz channel BW, FSK	-87 dBm @ BER = 10^{-3} (or -85 dBm @ BER = 10^{-4}) -91 dBm @ BER = 10^{-3} (or -89 dBm @ BER = 10^{-4}) -101 dBm @ BER = 10^{-3} (or -99 dBm @ BER = 10^{-4}) See note 1
Texas Instruments/Chipcon CC2420 [i.27]	250 kbps, 2,6 MHz channel BW, 802.15.4 PHY	-90 dBm @ PER = 1 % (or -89 dBm @ BER = 10^{-4}) See note 2
Nordic nRF24LU1+	2 Mbps, 2 MHz channel BW, GFSK 1 Mbps, 1 MHz channel BW, GFSK 250 kbps, < 1 MHz channel BW, GFSK	-82 dBm @ BER = 10^{-3} (or -80 dBm @ BER = 10^{-4}) -85 dBm @ BER = 10^{-3} (or -83 dBm @ BER = 10^{-4}) -94 dBm @ BER = 10^{-3} (or -92 dBm @ BER = 10^{-4}) See note 1
Freescale MC13202	250 kbps, 2,6 MHz channel BW, 802.15.4 PHY	-92 dBm @ PER = 1 % (or -91 dBm @ BER = 10^{-4}) See note 2
NOTE 1: A 2 dB offset is added to get a conservative estimation of the sensitivity @ BER = 10-4. NOTE 2: A 1 dB offset is added to get a conservative estimation of the sensitivity @ BER = 10-4.		

A similar analysis could be performed for MBANSs with a bandwidth less than 1 MHz. It should be noted that both the maximum radiated power and the noise power are proportional to the bandwidth in that case and the link margin results will be the same as the above analysis.

In summary, 0 dBm for BW $\geq$ 1 MHz and 10 log (B) dBm for B < 1 MHz (where B is the MBANS emission bandwidth in MHz) maximum radiated power limits for the healthcare facility sub-band are sufficient to meet link robustness requirements of MBANS short-range in-hospital applications.

Moreover, such power limits for the healthcare facility sub-band are low enough to significantly alleviate possible in-band interference to incumbent users. Together with frequency agility and limited duty cycle, the proposed power limits can elegantly support the compatibility with users of the frequency band.

The low power limits also facilitate frequency reuse inside healthcare facilities, where, in comparison with patients' homes, the higher density of MBANS devices expected makes it most necessary.

A.1.1.2.3 Link Budget Analysis for Home Healthcare MBANS Applications

In a home monitoring case, a long communication range is highly desirable to provide greater mobility to MBANS users within their homes and minimize the required base installation cost. Usually, one MBANS hub device may cover multiple rooms, as shown in figure A.4, and therefore, a higher emission power limit for the location independent sub-band is preferred from home healthcare perspective. Also, a higher power limit is needed to cope with an adverse event that may cause a patient to fall on the transmitter, causing significant signal attenuation. Moreover, in case of MBANS operation in the 2 360 MHz to 2 400 MHz or 2 483,5 MHz to 2 500 MHz band, a higher radiated power is helpful to counteract possible interference introduced by the out-of-band emission from adjacent band users, e.g. ubiquitous high-power 2,4 GHz generic SRD band devices (Wi-Fi radios, Bluetooth® devices, etc.).

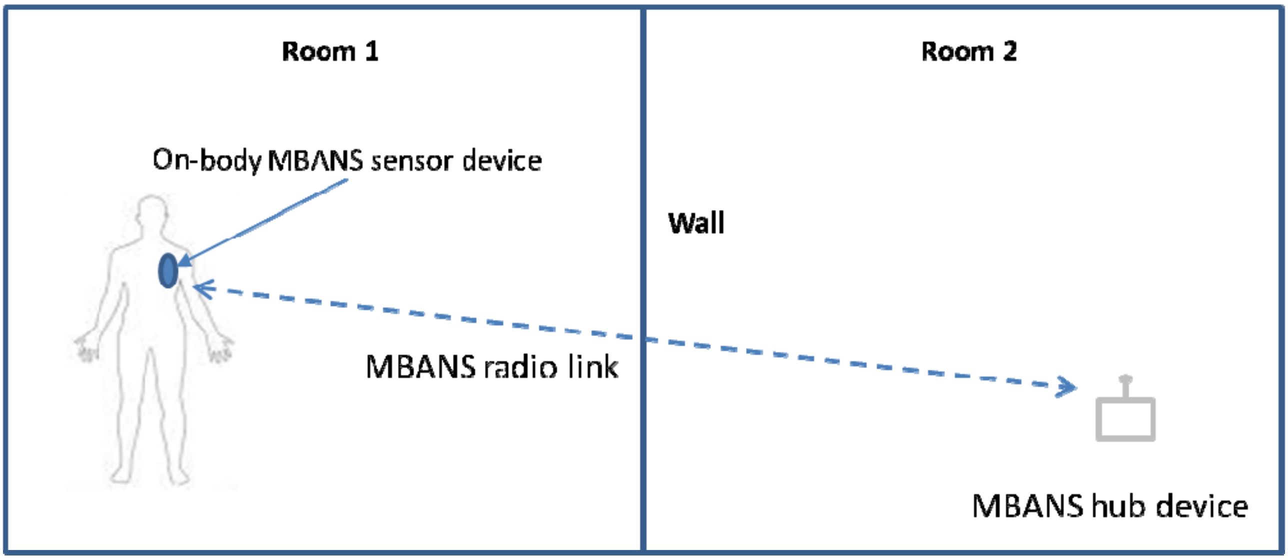


Figure A.4: Home healthcare MBANS with external hub device

In this scenario, a communication range of 10 meters is a reasonable design objective for home monitoring applications. First, a link budget analysis is given for the 0 dBm transmission power case, In this link budget analysis, the following assumptions are used: AWGN channel model, 10 meter communication range, 0 dBi TX and RX antenna gains, free-space path loss, central frequency of 2 500 MHz (worst case), 10 dB noise figure and 6 dB implementation loss. Since most of the home monitoring applications that require long ranges are usually low-rate applications, we assume the data rate is 31,25 kbps. Two typical modulation schemes are studied, O-QPSK and FSK with modulation index 0,5. It should be noted that the analysis does not include excess noise from adjacent band devices. Table A.5 summarizes the link budget analysis results.

Table A.5: Link budget analysis for in-home MBANS applications with 0 dBm_TX power

Parameter	O-QPSK	FSK
Information data rate (R_b) [Kbps]	31.25	31.25
Average TX power (P_T)[dBm]	0	0
TX antenna gain (G_T)[dBi]	0	0
Center frequency (f_c) [MHz]	2500	2500
Path loss at 10 meter, $L_1 = 20\log_{10}\{(4\pi f_c d/(3\times 10^8))\}[dB]$	60.4	60.4
Human body blockage loss (L_2)[dB]	30	30
building attenuation (L_3)[dB]	20	20
RX antenna gain (G_R) [dBi]	0	0
RX power ($P_R = P_T + G_T + G_R - L_1 - L_2 - L_3$) at $10m$	-110.4	-110.4
Average noise power ($N = -174 + 10 * log_{10}(BW)$) [dBm]	-128	-129.1
RX noise figure referred to the antenna terminal (N_F) [dB]	10	10
Total noise power ($P_N = N + N_F$) [dBm]	-118	-119.1
Required Minimum SNR (S) [dB]	8.4	11.4
Implementation loss (I) [dB]	6	6
Link Margin ($M = P_R - P_N - S - I$), $d = 10$m [dB]	-6.8	-8.7

In the above analysis, a 30 dB loss and another 20 dB loss are included to represent the human body blockage loss, which could happen when a patient falls on MBANS devices in an adverse event, and extra attenuation introduced by barriers (e.g. walls and doors), respectively. Some barrier attenuation values can be found in the online document [i.18]. 20 dB is a practical choice to cover typical use cases. From the above analysis, one can see that 0 dBm is not enough to provide a 10-meter communication range. For both cases, the achieved link margins are negative, which means more transmission power is needed to achieve the desired coverage.

Increasing the transmission power to 13 dBm would provide sufficient link margin for home monitoring applications, as demonstrated by the link budget analysis in table A.6. In the both cases, more than 4 dB link margins are achieved. Therefore, it is proposed to increase the transmission power limit to 13 dBm (20 mW) in the location independent sub-band. With this power limit, MBANS radios can provide reasonable coverage, link performance, and data rates for home monitoring applications and overcome out of band emission inference from nearby adjacent band devices. With dynamic transmit power control techniques, MBANS radios would only use such power levels when needed. For example, MBANS users would stay in their houses most of the time and MBANS radios could significantly lower the transmission power since the building attenuation would be much less than 20 dB. This, together with low duty cycle (< 2 %), would effectively mitigate interference to other services.

Table A.6: Link budget analysis for in-home MBANS applications with 13 dBm _TX power

Parameter	O-QPSK	FSK
Information data rate (R_b) [Kbps]	31.25	31.25
Average TX power (P_T)[dBm]	13	13
TX antenna gain (G_T)[dBi]	0	0
Center frequency (f_c) [MHz]	2500	2500
Path loss at 10 meter, $L_1 = 20\log_{10}\{(4\pi f_c d/(3\times 10^8))\}[dB]$	60.4	60.4
Human body blockage loss (L_2)[dB]	30	30
building attenuation (L_3)[dB]	20	20
RX antenna gain (G_R) [dBi]	0	0
RX power ($P_R = P_T + G_T + G_R - L_1 - L_2 - L_3$) at $10m$	-97.4	-97.4
Average noise power ($N = -174 + 10 * log_{10}(BW)$) [dBm]	-128	-129.1
RX noise figure referred to the antenna terminal (N_F) [dB]	10	10
Total noise power ($P_N = N + N_F$) [dBm]	-118	-119.1
Required Minimum SNR (S) [dB]	8.4	11.4
Implementation loss (I) [dB]	6	6
Link Margin ($M = P_R - P_N - S - I$), $d = 10$m [dB]	6.2	4.3

A.1.2 Emission Bandwidth

A.1.2.1 Proposed Emission Bandwidth

a) The maximum authorized emission bandwidth is 5 MHz.

b) The emission bandwidth is determined by measuring the width of the modulated emission between the frequencies furthest above and furthest below the frequency of maximum power where the emission power drops 20 dB with respect to its maximum level.

A.1.2.2 Technical Justification

A limit for maximum emission bandwidth that would enable a greater capacity to manage evolving medical applications is preferred. A higher or flexible bandwidth would allow more applications and shorter duty cycles (that would reduce power consumption). It is proposed to adopt a bandwidth limit of 5 MHz (at 20 dB down) for the following reasons.

- **The proposed maximum authorized emission bandwidth would provide flexibility and technology neutrality, allowing the industry to develop appropriate MBANS solutions, especially to leverage most of the available 2,4 GHz generic SRD band solutions to produce relatively low-cost MBANS devices.**

The commercial acceptance of Medical Body Area Network Systems (MBANSs) will depend on manufacturers producing small low-cost (e.g. low enough to be disposable in some cases) sensors. Doing so in turn will depend on the manufacturers' ability to leverage low cost, off-the-shelf integrated circuits that can be used directly or at least that can be modified or adapted at relatively modest cost and complexity (e.g. minimal external discrete circuitry). One of the benefits of using a frequency band within the 2 360 MHz to 2 500 MHz range for MBANSs is the capability to economically leverage multiple off-the-shelf 2,4 GHz short range connectivity solutions to achieve economies of scale. It is expected that, at relatively moderate effort/cost, low-power short-range radios from 2,4 GHz generic SRD band can be re-tuned to work on other frequencies in the 2 360 MHz to 2 500 MHz range with similar receiver sensitivity performance. Some major 2,4 GHz generic SRD band connectivity solutions, which are commercially available and have been widely deployed, and their parameters, are listed below.

Table A.7: Examples of available 2,4 GHz generic SRD technologies

2,4 GHz Solutions	Emission Bandwidth (20 dB bandwidth)	Supported Raw Data Rates
Bluetooth®	~1 MHz	1 Mbps (2 and 3 Mbps for enhance data rate modes)
ZigBee™	~2,6 MHz	250 Kbps
Nordic Semiconductors Proprietary solutions (i.e. nRF24L01+)	< 1 MHz for 250 Kbps mode ~1 MHz for 1 Mbps mode ~2 MHz for 2 Mbps mode	250 Kbps 1 Mbps 2 Mbps

- **A 5 MHz maximum emission bandwidth creates flexibility to cater to the diverse needs of MBANS applications, especially high data rate and low power consumption needs.**

MBANS applications have a large variety of requirements on data rate, link reliability, delay tolerance, and lifetime. A 5 MHz maximum emission bandwidth will provide scalable data rate modes to meet a wide range of requirements.

Technical parameters of several typical MBANS applications are shown in table A.8.

Table A.8: Some technical parameters of several typical MBANS applications

Application	Target data throughput	P2P Latency	Application Bit Error Rate (BER)	Desired Battery Lifetime
ECG (Multi-lead)	96 Kbps	< 250 ms	$< 10^{-6}$	> 1 week
EMG	384 Kbps	< 250 ms	$< 10^{-6}$	> 1 week
O_2/CO_2/BP/ Temp/Respiration/ Glucose monitoring, accelerometer	< 10 Kbps	< 250 ms	$< 10^{-6}$	> 1 week

For example, a classic multi-lead ECG node may require as high as 96 kbps application level throughput to forward its ECG signal to a hub device in a real-time cardiac monitoring system while at the same time, the desired battery lifetime is more than a week. Assuming 25 % duty cycle and 40 % protocol overhead (including physical layer, MAC layer and application layer protocols), the required raw data rate per MBANS should be at least 640 Kbps. For the Electromyogram (EMG) case, the required raw data rate per MBANS should be at least 2,56 Mbps. In the future, the required raw data rates could be even higher to achieve better monitoring performance. To provide such a high data rate with a long battery lifetime (> 1 week) and a very low error rate, a broad maximum emission bandwidth is preferred. If a small maximum emission bandwidth, such as 1 MHz, is adopted, a short-range wireless connectivity solution for MBANS applications would need to achieve 3 bits/s/Hz (or even higher in the future) spectrum efficiency. To design such wireless systems could be very challenging considering the strict link reliability and power consumption requirements since more sophisticated modulation and/or coding schemes are needed. This would increase MBANS device implementation complexity, the peak power consumption and also the average power consumption, resulting in it being impractical to use a small size battery or energy harvesting components in a MBANS device, which is especially undesirable for disposable sensor applications. However, a 5 MHz emission bandwidth can relax the required spectrum efficiency to less than 1 bit/s/Hz, which could be achieved with very simple modulation schemes, like GFSK, FSK and offset-QPSK. Those modulation schemes are very mature and have potential to further improve raw data rates to meet the requirements of future MBANS applications.

- **Broad emission bandwidth can significantly prolong MBANS device battery life via limited duty cycle operations.**

Battery life is an important factor to be considered when designing a MBANS. A higher emission bandwidth (e.g. 5 MHz) enables MBANS devices to operate at higher data rate modes (e.g. > 3 Mbps) and therefore achieve low duty-cycle operation. Low duty-cycle operation facilitates low average power consumption and long battery life. For example, the Nordic nRF24L01+ chipset has a power consumption of 34 mW (0 dBm transmit power) either with 1 Mbps (1 MHz bandwidth) or with 2 Mbps (2 MHz bandwidth) in the transmission mode, a power consumption of 39,3 mW with 1 Mbps and 40,5 mW with 2 Mbps in the receive mode, and a power consumption of 78 µW in the standby mode (standby-I mode). There is almost no difference between the 1 Mbps option and the 2 Mbps option in terms of average power consumption in their TX/RX modes. However, the 2 Mbps option can reduce the duty cycle almost by half and therefore double the battery lifetime compared to the 1 Mbps option.

- **Broad maximum emission bandwidth is crucial to accommodate health-critical MBANS services.**

Data loss could cause severe problems in MBANS applications and usually strict link reliability is required. A wide emission bandwidth can enable the link reliability required by healthcare professionals. A wide bandwidth could be used to achieve high spreading gain via spectrum spreading technologies or coding gain via simple channel coding while still maintaining a high enough rate to support MBANS applications. For example, simulation results of data rate modes are shown in figure A.5. The 250 Kbps mode uses the direct sequence spectrum spreading (DSSS) scheme with Offset QPSK (O-QPSK) modulation, which is used in IEEE 802.15.4. The 500 Kbps mode uses the DSSS scheme with O-QPSK modulation, as defined in [i.19]. The 1 Mbps mode uses O-QPSK modulation with a ½-rate repetition code (repeat each symbol twice). The 2 Mbps mode just uses O-QPSK modulation. All the above four data rate modes have the same 20 dB emission bandwidth, which is around 2.6 MHz. From the simulation results, one can see the 250 Kbps, 500 Kbps, and 1 Mbps modes can achieve about 8,3 dB; 5,2 dB and 3 dB signal-to-noise-ratio (SNR) gain at the bit error rate of 10^{-4} respectively, compared to the 2 Mbps data rate mode. This performance-rate tradeoff can be used by a MBANS device to adaptively adjust its transmission to achieve medical- grade performance with low power consumption. When the link quality is good, a MBANS transmitter can use a high data rate mode to achieve low duty-cycle, therefore low power consumption; while when the link quality becomes worse, for example, due to patient body movement or interference from other system, a MBANS transmitter can use a low data rate mode to achieve performance gain, thereby ensuring a QoS appropriate for medical use.

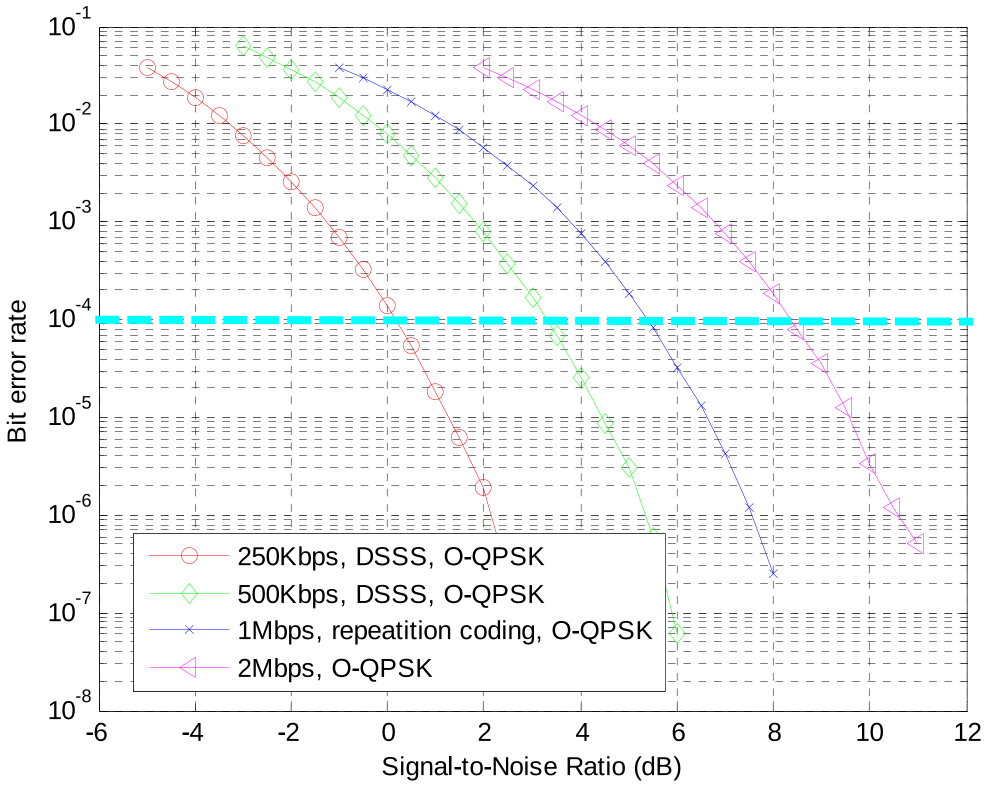


Figure A.5: BER performance of O-QPSK with different data rates

Second, higher data rates (achieved with a wide bandwidth) enable MBANS devices to finish their transmission in a short period so that they can do retransmissions if needed in the same or other channels to mitigate the effects of external interference and channel fading while still maintaining the point-to-point (P2P) latency requirements.

- **Broad emission bandwidth can be used to improve compatibility among multiple MBANS devices and with other users in the same frequency band.**

Limited duty-cycle operation reduces the on-air time of MBANS devices and therefore reduces the possibility of interference to other co-channel users. This also enables multiple MBANSs to co-exist in the same channel with a low collision possibility.

Furthermore, a high bandwidth can be utilized to achieve spreading gain so that a lower transmission power could be used, which in turn reduces the interference power to other co-channel users or other MBANSs. This could improve the spectrum reuse efficiency.

- **Broad emission bandwidth is feasible from practical implementation aspects.**

An emission bandwidth higher than 5 MHz may complicate MBANS radio implementation, thereby increasing cost and power consumption. If a MBANS has a bandwidth that is wider than the coherence bandwidth of typical MBANS channels, it would require a complicated equalizer to deal with possible multipath fading (or frequency selective fading) and thus increase cost. To obtain a simple implementation, it is preferable to adopt a maximum emission bandwidth that is smaller than the coherence bandwidth of typical MBANS channels. Based on the results presented in [i.28], it is expected that an MBANS channel with a lower central frequency in the 1 785 MHz to 2 500 MHz range usually has a smaller root mean square delay spread and thus a larger coherent bandwidth, since lower frequencies diffract more easily around human body. Therefore, channel measurement results for the 2,45 GHz body area networks (BAN) in the literature can be used to conservatively estimate channel coherent bandwidth of an MBANS channel in the 1 785 MHz to 2 500 MHz frequency range. In [i.20] the authors conducted extensive measurements to study the channel coherence bandwidth of 2,45 GHz BAN channels under different scenarios. It is shown there that in most cases, the coherence bandwidth is at least 5 MHz. That means that with a channel bandwidth of 5 MHz or less, the frequency selective fading effect is negligible and no equalizer is required. Therefore, 5 MHz is a good choice for the maximum emission bandwidth in the sense of simplifying MBANS radio implementation and reducing costs.

Moreover, a bandwidth that is too large usually requires a high sampling rate and signal processing speed, which could increase power consumption. Thus, a very large bandwidth is not desired for MBANS applications since a long battery life is a priority. 5 MHz bandwidth is usually acceptable for those low power applications. For example, an IEEE 802.15.4 radio has a bandwidth of 2,6 MHz while achieving reasonably low power consumption.

In summary, 5 MHz maximum emission bandwidth provides a good balance of all the above implementation considerations. This allows for future advancement in technology.

A.1.3 Total amount of Spectrum Designation

A designation of the 40 MHz spectrum is proposed since such amount of spectrum requested will maximize opportunities for the compatibility of MBANSs and other services to avoid interference through frequency separation, support the co-existence of multiple MBANSs, and provide the spectrum needed for future innovation.

- **Designating the 40 MHz of spectrum is necessary to lessen interference potential and promote device innovation.**

a) 40 MHz of spectrum, together with co-existence mechanisms, will enable MBANS devices to efficiently share spectrum with other services without causing interference.

A 40 MHz spectrum designation plays a key role in enabling MBANS devices achieving 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 co-channel interference with other services.

A 40 MHz spectrum would provide MBANS devices enough spectrum choices to enable interference-free operations of radio services while maintaining a reliable MBANS radio link. With frequency agility, MBANS devices can detect the operations of such services. On detecting another user, MBANS devices can change channels to avoid mutual interference. A 40 MHz designation is critical to support MBANS operations in dense deployment scenarios while providing adequate frequency separation for protection of other services. It should be noted that frequency agility may require detecting the energy emitted by other users, which may lead to an increase in power consumption.

Even in the rare case that MBANS devices are not able to detect other users' operations, a larger spectrum designation would reduce the probability that a MBANS would operate within the channel occupied by another user, and therefore a larger designation will mitigate the aggregated interference to other services. For example, if an aeronautical telemetry receiver has a bandwidth of 5 MHz and the total designated MBANS spectrum is 40 MHz, then each MBANS has a probability of 0,125 (5/40) to operate totally within the ATS channel. If there are 100 active MBANSs in a hospital and they select their MBANS channels randomly (with a uniform distribution) and independently, then on average there would be 12,5 MBANSs operating totally within the ATS channel. In the same scenario, if the designated MBANS spectrum is 30 MHz, there would be on average 16,7 MBANSs operating totally within the ATS channel. A larger spectrum designation will therefore reduce aggregated power within any channel and is preferred.

Moreover, a 40 MHz spectrum designation will enable MBANS equipment to operate with very low aggregation of radiated power and duty cycle and thus significantly alleviate possible interference to other services. With a 40 MHz spectrum designation, MBANS radios can use wide bandwidth to achieve high data rate and improve performance via techniques like spreading spectrum and coding. High data rate will reduce MBANS operation duty cycle and performance gain will reduce the required transmission power, which results in greatly reduced aggregated interference to other services.

Regarding interference from other services to MBANS devices, it should be noted that a significant MBANS channel bandwidth (5 MHz) together with the need of sufficient channel spacing and several channel choices imply that a significant amount of spectrum, such as 40 MHz, is necessary. Such combination of channel bandwidth and spectrum amount significantly enhances MBANS link performance and thereby improves immunity to in-band interference from other services. With properly designed spectrum spreading and/or channel coding schemes, a high link margin can be achieved. Such high link margin will enable MBANSs to still maintain normal operations within the current channel with guaranteed QoS performance, even in presence of moderate in-band interference. Usually, a modest physical separation from other co-channel users would reduce the interference to MBANSs to levels below the tolerable threshold. In the case that in-band interference signal is detectable by MBANS devices, the MBANS frequency agility and contention-based protocol characteristics will allow MBANSs to switch to a cleaner channel and/or avoid interference. Again, a 40 MHz spectrum designation would play a key role in this situation by maximizing the chances that clear channels will be available to MBANSs.

b) 40 MHz spectrum designation is needed to support MBANS co-existence in high-density deployment scenarios

The amount of spectrum designation should be capable of supporting MBANS operations with simple radios in high-density deployment cases. It is envisioned that in some cases, such as waiting areas of Emergency Rooms (ERs), elevator lobbies, preparatory areas for imaging services etc., multiple patients with active MBANSs could gather together and frequency coordination and/or contention-based protocols would be required to coordinate the distributed MBANS operations in order to avoid interference among the MBANS devices. Frequency-hopping and listen-before-talk protocols are two popular unsynchronized coordination schemes that are suitable for MBANS applications. In a GE Healthcare analysis previously submitted to the FCC, the performance of a frequency hopping based coordination scheme was studied and the conclusion was that approximately 18 MHz is required to support the co-existence of ten heavily loaded and mobile MBANSs with acceptable packet loss probability Therefore, it is concluded there that "a 40 MHz allocation would provide sufficient bandwidth for MBANS devices utilizing contention-based protocols to operate with sufficiently low packet error rate and without impact to primary radio service users" [i.1].

Here, an analysis considered the performance of another popular contention-based protocol, listen-before-talk or CSMA (channel sensing multiple access) under a wireless ECG MBANS scenario. The ECG MBANS studied here has a star topology, shown in figure A.6, and consists of a multi-lead ECG sensor, a SpO2 sensor, and a hub device. The assumed traffic patterns are:

- ECG data: 96 kbps => 1 packet per 8 ms, 111 bytes/packet (with 15 bytes PHY/MAC overhead, based on IEEE 802.15.4 packet structure)
- SpO2 data: 1,76 kbps => 1 packet per 0,5 s, 125 bytes/ packet (with 15 bytes PHY/MAC overhead)
- Command data : one packet per 30 s, 133 bytes/packet (with 15 bytes PHY/MAC overhead)

The CSMA/CA scheme adopted in IEEE 802.15.4 non-beacon mode is one of the proven listen-before-talk schemes and is used here to study the co-existence performance. Some parameters used are:

- IEEE 802.15.4 packet structure: 15 bytes overhead (including PHY and MAC)
- Maximum back-off number N_bo = 5
- Contention window size: fixed to 127
- Error free transmission (reasonable assumption considering low bit error rate requirement)
- Two raw PHY data rates studied: 1 Mbps and 2 Mbps
- No ACK to simplify the analysis

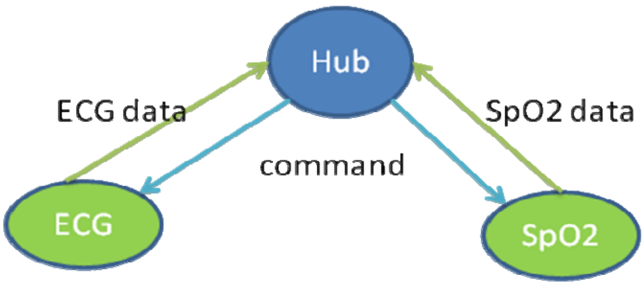


Figure A.6: MBANS Star topology

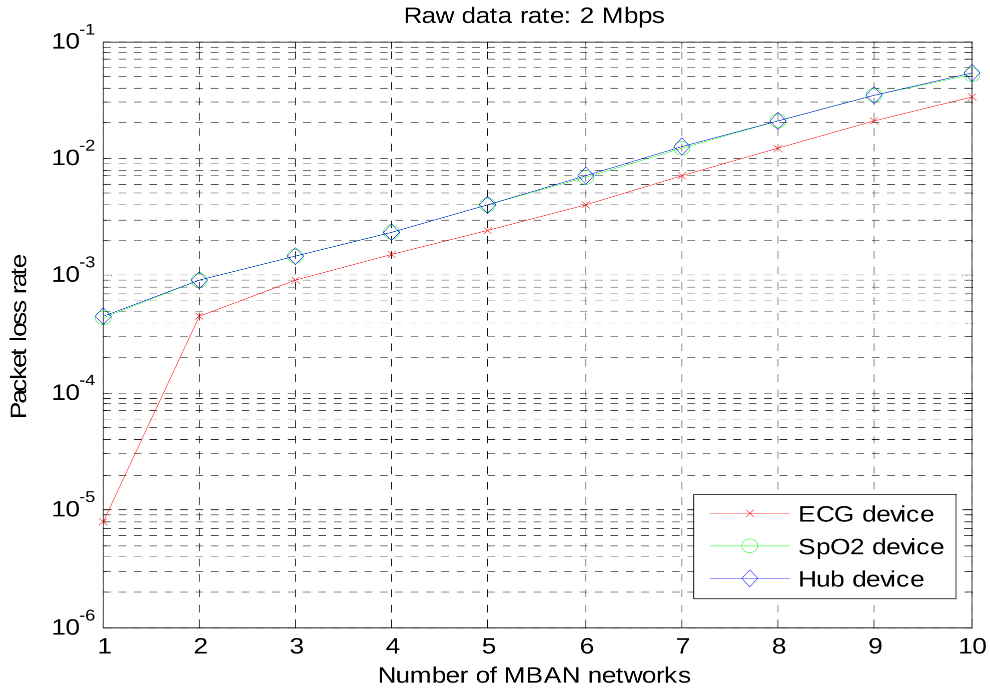


Figure A.7: Packet loss rate performance with 2 Mbps raw data rate

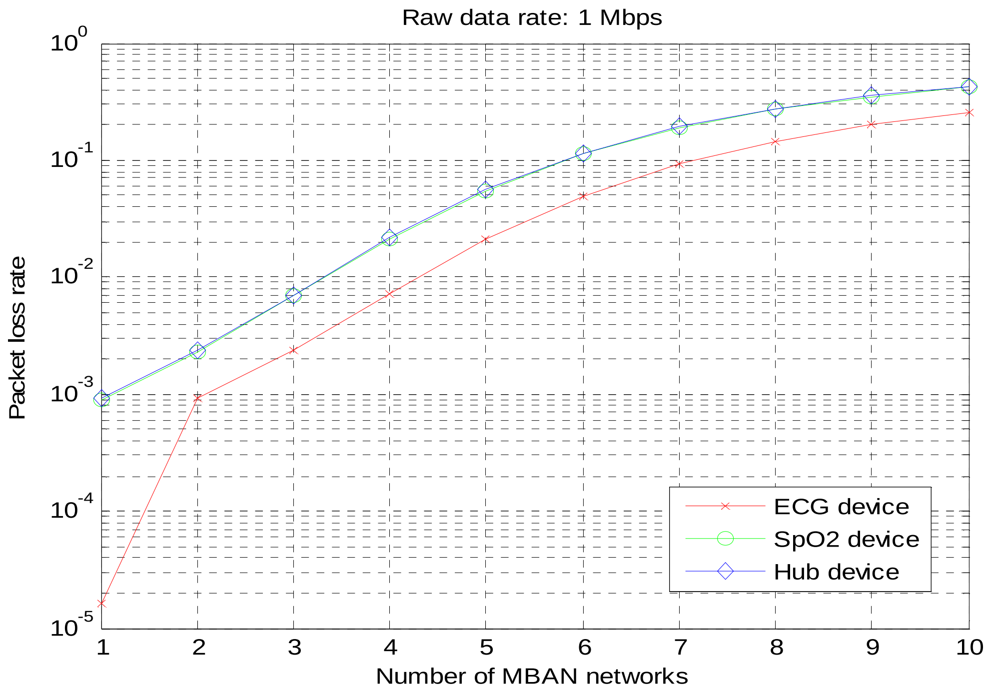


Figure A.8: Packet loss rate performance with 1 Mbps raw data rate

The analysis is based on the results in [i.21]. Here we assume that a packet loss rate, which is caused only by collisions among multiple MBANS devices, of no larger than 10^{-3} is acceptable for MBANS applications. This is a reasonable performance criteria considering the importance of medical data in high acuity applications.

The above figures demonstrate that if the physical layer raw data rate is 1 Mbps, then one channel can support only one MBANS. If two MBANSs co-exist in the same channel, the packet loss rate of a hub device or SpO2 device would exceed 10^{-3}. Therefore, to support ten ECG MBANSs, 10 non-overlapping channels are required. To achieve 1 Mbps with simple radio technology, the channel bandwidth should be at least 1 MHz (~1 MHz for GFSK/FSK with modulation index 0,5 [i.26], ~1,3 MHz for O-QPSK). Therefore, at least 10 MHz spectrum would be needed. Taking into consideration the guard band at each edge of the spectrum, approximately 12 MHz to 15 MHz of spectrum would be required.

If the physical layer raw data rate is 2 Mbps, then one channel can support at most two MBANSs. If more than two MBANSs exist on the same channel the packet loss rate of a hub device or SpO2 device would be higher than 10^{-3}. Therefore, to support 10 ECG MBANSs, 5 non-overlapping channels are required. To achieve 2 Mbps with simple radio technology, the channel bandwidth should be at least 2 MHz (~2 MHz for GFSK/FSK with modulation index 0,5; ~2,6 MHz for O-QPSK [i.27]). Therefore, at least 10 MHz of spectrum would be needed. Taking into consideration the guard band at each edge of the spectrum, approximately 12 MHz to 15 MHz spectrum would be required.

Based upon these analyses, it is concluded that, "a 40 MHz allocation would provide sufficient bandwidth for MBANS devices utilizing contention-based protocols to operate with sufficiently low packet error rate and without impact to primary radio service users" is also true for devices utilizing listen-before-talk contention-based protocol.

For home applications, a 10 MHz bandwidth is sufficient to support at least 2 MBANSs, even if a 6 MHz amateur radio signal is protected. As previously mentioned, the remaining bandwidth should be exclusively used inside healthcare facilities, where a higher density of MBANSs is expected. This restriction can be easily and automatically enabled by means of a healthcare facility mechanism which ensures that operation in such bands is suppressed outside a healthcare facility.

a) 40 MHz spectrum designation affords meaningful frequency diversity that would allow MBANS devices to use lower transmission power and therefore mitigate potential interference to other services.

As explained, channel measurement results from the 2,4 GHz body area networks (BAN) literature can be used to study the channel coherent bandwidth characteristics of MBANS channels in the 1 785 MHz to 2 500 MHz range. Based on the measurement results available in the literature, the coherence bandwidth of typical MBANS channels is much less than 40 MHz. The authors of [i.20] conducted extensive measurements to study the channel coherence bandwidth of 2,4 GHz BAN channels under different scenarios. It is shown in [i.20] that, in most cases, the coherence bandwidth is at least 5 MHz. GE Global Research measurements of on-body and body-coupled propagation with body-worn, printed antennas also reveal coherence bandwidths of those channels are much less than 40 MHz [i.1]. Therefore, 40 MHz spectrum designation would allow for good frequency diversity, useful for MBANS devices to combat multipath fading. For example, the retransmission of short data packets on multiple frequency channels is an effective frequency diversity technique that is readily implemented by wireless medical devices using commercially available transceiver chips. The achieved frequency diversity gain would enhance MBANS link quality and allow MBANS devices to use lower transmission power. This would be helpful to mitigate potential interference to other services.

In summary, a 40 MHz designation, with 10 MHz for out-of-healthcare-facility use, is sufficient to support multiple MBANS co-existence with currently available contention-based protocols, error correction/detection mechanisms and temporal/frequency diversity.

b) A contiguous 40 MHz spectrum designation would provide flexibility for future MBANS innovations

A designation of 40 MHz of contiguous spectrum (only possible in the 2 360 MHz to 2 400 MHz and 2 400 MHz to 2 483,5 MHz bands) would benefit future MBANS innovations, which may require lower cost, power consumption, higher data rate, or other features. In particular, a contiguous spectrum designation would simplify MBANS radio RF design and therefore reduce cost and power consumption.

A.2 RF safety considerations

MBANS devices are usually body worn devices and should be subjected to the RF exposure rules. For the 1 785 MHz to 2 500 MHz frequency range, the localized Specific Absorption Rate (SAR) limit for head and trunk is 2 W/kg and the localised SAR limit for limbs is 4 W/kg, where the localised SAR averaging mass is any 10 gram of contiguous tissue [i.25].

In the worst case, a MBANS device with a transmission power of P mW may generate a localised SAR in 10 gram tissue of P/10 mW/g. Therefore, to meet the SAR limits defined in Council Recommendation 1999/519/EC [i.25], the transmission power P should satisfy:

$$P/10 < 2\,000/1\,000 \text{ mW/g, which is equivalent to } P < 20 \text{ mW.}$$

The proposed maximum radiated power limits for the healthcare facility and the location independent sub-bands are limited to 1 mW and 20 mW respectively. The limited duty cycle of MBANS devices (< 25 %) would reduce the average MBANS transmission power below 20 mW and produce RF exposure well under the SAR limits defined in [i.25].

Annex B: Bibliography

ECC Report 100: "Compatibility studies in the band 3400- 3800 MHz between broadband wireless access (BWA) systems and other services".

EC Decision 2006/771/EC: "Harmonisation of the radio spectrum for use by short-range devices and its subsequent amendments".

ITU-R Report SM.2153: "Technical and operating parameters and spectrum use for short range radiocommunication devices".

History

Document history		
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