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Reference

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Foreword

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

Modal verbs terminology

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Introduction

The present document includes necessary information to support the co-operation under the MoU between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Post and Telecommunications Administrations (CEPT).

Ultra Wide Band technologies enable a very broad new set of applications in the field of medical, assisted living, eHealth and wellness. The deployment of UWB in the field can be split into the following applications:

- Communication applications.
- Sensor and imaging applications.
- Hybrid application as a combination of sensor and communications.

The broad range of potential applications of the technology will be covered in this TR in order to classify the requirements and to identify the potential need of specific regulatory activities on CEPT and standardization activities in ETSI.

The present document has been created by TC ERM TGUWB.

1 Scope

The present document provides information on the intended applications, the technical parameters, the relation to the existing spectrum regulation and additional new radio spectrum requirements for UWB equipment for the operation in medical, wellness and assisted living environments and applications in the band below 10 GHz.

The applications can be divided in 3 different categories of medical applications:

- Category A: Communication Devices in controlled medical environments.
- Category B: Contact based sensing and imaging devices.
- Category C: Off-body/off-material sensing and imaging devices.

The application environments of the presented technologies will cover home environments for assisted living applications, hospital environments including doctor's surgeries and automotive environments.

The present document includes necessary information to support the co-operation between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Post and Telecommunications Administrations (CEPT), including:

- Detailed market information (annex A).
- Technical information (annex B).
- Relation to existing spectrum regulation (annex C).

2 References

2.1 Normative references

Normative references are not applicable in the present document.

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] ETSI EN 303 883 (V1.1.1) (02-2016): "Short Range Devices (SRD) using Ultra Wide Band (UWB); Measurement Techniques".

[i.2] ETSI EN 302 065-1 (V2.1.1) (11-2016): "Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 1: Requirements for Generic UWB applications".

[i.3] ETSI EN 302 065-2 (V2.1.1) (11-2016): "Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 2: Requirements for UWB location tracking".

[i.4] ETSI EN 302 065-3 (V2.1.1) (11-2016): "Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 3: Requirements for UWB devices for ground based vehicular applications".

[i.5] ETSI EN 302 065-4 (V1.1.1) (11-2016): "Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 4: Material Sensing devices using UWB technology below 10,6 GHz".

[i.6] CEPT ECC/DEC/(06)04 of 24 March 2006 amended 9 December 2011: "The harmonised conditions for devices using Ultra-Wideband (UWB) technology in bands below 10.6 GHz".

[i.7] Commission Decision 2007/131/EC of 21 February 2007 on allowing the use of the radio spectrum for equipment using ultra-wideband technology in a harmonised manner in the Community (notified under document number C(2007) 522).

[i.8] Commission Decision 2009/343/EC of 21 April 2009 amending Decision 2007/131/EC on allowing the use of the radio spectrum for equipment using ultra-wideband technology in a harmonised manner in the Community (notified under document number C(2009) 2787).

[i.9] Commission Decision 2014/702/EU of 7 October 2014 amending Decision 2007/131/EC on allowing the use of the radio spectrum for equipment using ultra-wideband technology in a harmonised manner in the Community (notified under document C(2014) 7083).

[i.10] ECC/DEC/(07)01: "ECC Decision of 30 March 2007 on specific Material Sensing devices using Ultra-Wideband (UWB) technology (amended 26 June 2009)".

[i.11] ECC Report 120 (March 2008): "ECC Report on Technical requirements for UWB DAA (Detect and avoid) devices to ensure the protection of radiolocation in the bands 3.1-3.4 GHz and 8.5-9 GHz and BWA terminals in the band 3.4-4.2 GHz".

[i.12] CEPT Report 45: "Report from CEPT to the European Commission in response to the Fifth Mandate to CEPT on ultra-wideband technology to clarify the technical parameters in view of a potential update of Commission Decision 2007/131/EC"; Report approved on 21 June 2013 by the ECC.

[i.13] CEPT/ECC Report 64: "The protection requirements of radio communications systems below 10,6 GHz from generic UWB applications", Helsinki, February 2005.

[i.14] CEPT Report 34: "Report B from CEPT to European Commission in response to the Mandate 4 on Ultra-Wideband (UWB); Final Report on 30 October 2009 by the Electronic Communications Committee (ECC) within the European Conference of Postal and Telecommunications Administrations (CEPT)".

[i.15] ECC Report 94: "Technical requirements for UWB LDC devices to ensure the protection of FWA Systems" Nicosia, December 2006.

[i.16] ECC Report 123: "The impact of Object Discrimination and Characterization (ODC) applications Using Ultra-Wideband (UWB) technology on radio services", Vilnius, September 2008.

[i.17] ETSI TR 103 181-1 (V1.1.1) (07-2015): "Short Range Devices (SRD) using Ultra Wide Band (UWB); Technical Report; Part 1: UWB signal characteristics and overview CEPT/ECC and EC regulation".

[i.18] ETSI TR 103 181-2 (V1.1.1) (06-2014): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD) using Ultra Wide Band (UWB);Transmission characteristics; Part 2: UWB mitigation techniques".

[i.19] M. Mahler, et.al.: "Radar sensor to DETERMINE POSITION And PHYSIOLOGICAL PARAMETERS OF A PERSON IN A VEHICLE", European Microwave Week 2002, Milano.

[i.20] C. G. Bilich: "Bio-medical sensing using ultra-wideband communications and radar technology: a feasibility study", in Proceedings of the 1st International Pervasive Health Conference and Workshops, Pervasive Health, pp. 1-9, November-December 2006.

[i.21] ECC Report 251: "The impact of UWB applications on board aircraft in the band 6-8.5 GHz on FS links used around airports and on EESS earth stations", 2016.

[i.22] ECC Report 234:"Analyses of LDC UWB mitigation techniques with respect to incumbent radiocommunication services within the band 3.1 to 3.4 GHz", 2015.

[i.23] ECC Report 175: "Co-existence study considering UWB applications inside aircraft and existing radio services in 3.1-4.8 GHz/6.0-8.5 GHz", 2012.

[i.24] ECC Report 170: "Specific UWB applications in the bands 3.4 - 4.8 GHz and 6 - 8.5 GHz LAES, LT2 and LTA", 2011.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in ETSI TR 103 181-1 [i.17] and ETSI TR 103 181-2 [i.18] apply.

3.2 Abbreviations

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

ADC	Analogue-to-Digital converter
BMA	Building Material Analyses
BWA	Broad Band Wireless Access
CAGR	Compound Annual Growth Rate
CEPT	Conference Européenne des Administrations de Postes et des Telecommunications
CMOS	Complementary Metal-Oxide Semiconductor
CVD	Cardiovascular diseases
DAA	Detect and Avoid
DAC	Digital-to-Analogue Converter
dBm	deciBel relative to 1 mW
DC	Direct Current
e.i.r.p.	equivalent isotropic radiated power
EC	European Commission
ECC	Electronic Communications Committee
ECG	Electrocardiograph
EEG	Electroencephalogram
EESS	Earth Exploration Satellite System
EIRP	Equivalent Isotropically Radiated Power
ERM	Electromagnetic compatibility and Radio spectrum Matters
EU	European Union
FR	Flame Retardant
FS	Fixed Systems
FWA	Fixed Wireless Access
LAES	Location tracking Application for Emergency and disaster Situations
LBT	Listen Before Talk
LDC	Low Duty Cycle
LF	Low Frequency
LNA	Low Noise Amplifier
LTA	Location Tracking Application
MCU	Micro Controller Unit
ODC	Object Discrimination and Characterization
OR	Operating Rooms
PCB	Printed Circuit Board
PRF	Pulse Repetition Frequency
PSD	Power Spectral Density
RAS	Radio Astronomy Service
RC	Remote Consensus
RF	Radio Frequency
RX	Receive
SIDS	Sudden infant death syndrome
SNR	Signal-to-noise ratio

SoC	System on Chip
SPI	Serial Peripheral Interface
SpO_2	peripheral capillary oxygen saturation
SRD	Short Range Device
TG	Task Group
TPC	Transmitter Power Control
TRP	Total Radiated Power
TX	Transmit
USB	Universal Serial Bus
UWB	Ultra Wide Band
WLAN	Wireless Local Area Network

4 Comments on the System Reference document

Void.

5 Presentation of systems or technologies

5.1 Background information

The European UWB regulation framework [i.6], [i.7], [i.8], [i.9] and [i.10] including the corresponding ETSI harmonised standards [i.1], [i.2], [i.3], [i.4] and [i.5] cover a broad range of applications deploying UWB technologies. The applications range from general communication, location and tracking, to material sensing. A significant number of medical applications with its specific requirements and mitigation factors have not been covered yet by corresponding entries into the regulatory document. In several cases the generic regulation cannot fulfil the performance requirements for the applications. The present document will give an overview over existing and planned UWB medical, ambient assisted living and wellness applications with the goal of identifying the regulatory requirements to allow these applications to be put onto the market.

5.2 Applications descriptions

5.2.1 Introduction

Ultra Wide Band technologies enable a very broad new set of applications in the field of medical, assisted living, eHealth and wellness. The deployment of UWB in the field can be split into the following applications:

- Communication applications.
- Sensor and imaging applications.
- Hybrid applications as a combination of sensor and communications.

Ultra wide band sensor and imaging technologies enable a new generation of devices, allowing the identification and classification of objects, in addition to detecting their presence and position. These devices do not require contact and can collect accurate data across distances of many meters.

Applications for such devices are widespread. The following list provides several examples:

- Discrimination between living and inanimate objects (human, animals, moving curtains, etc.) to avoid ambiguities.
- Assisted living: enabling/allow independent living or "aging in place":
  - Operational - assist care providers to be more effective.
  - Telemedicine - remote health monitoring and extended medical attention.

- Human Healthcare supervision:
  - Alarms for onset of symptoms associated with sudden Infant death syndrome (cot death prevention).
  - In-patient cardiopulmonary measurement and presence monitoring inside bed.
  - Out of position recognition of people in hospital beds.
  - At-home cardiovascular and pulmonary disease management.
  - Fetal monitoring during labour and delivery.
- Veterinary Applications:
  - Cardiopulmonary monitoring of animals during surgery.
  - Cardiopulmonary monitoring of animals during nutritional and pharmacological studies.
  - At-home cardiovascular and pulmonary disease management in animals.

Due to the large differences in the dielectric properties of air and tissue, non-contact based UWB sensors are typically best suited to measure phenomena that have a strong body surface component - i.e. breathing or motion. For many health and medical applications, non-contact based UWB sensors are acceptable. In contrast, for those applications where higher measurement accuracy is required or where the surface component is weak or non-existent, contact based UWB sensors are often necessary. With this model, there is effectively no air gap between sensor and patient, allowing most of the transmitted energy to propagate into the body and illuminate the anatomical structures of interest. For contact based sensors, degradation of SNR from tissue absorption is an important concern and operating at lower frequencies will minimize absorption.

One key benefit of contact based sensors is a significant reduction in undesired emissions when compared to non-contact sensors since a vast majority of the transmitted energy is directed into and absorbed by the body.

Ultra Wide Band communications technologies will be used for the transfer of medical data in the hospital and home environment. Some specific applications are listed below:

- Video data transmission in sensitive environments like operation rooms.
- High definition still image transmission.
- Portable X-Ray displays.
- Wireless connectivity between medical devices.

All these applications can benefit from the very low emissions and thus interference levels and the very high data rates possible with UWB technology. Furthermore, due to the very limited range of the wireless UWB transmission, additional protection of personal medical data can be guaranteed.

A third class of UWB enabled medical devices will combine [i.20] the two mentioned operations in a single device:

- Wireless connections of EEG sensors.
- Communicating health monitoring systems.
- Etc.

The proposed applications can be used in very restricted environments like operating rooms or intensive care stations but also in the home in order to support ambient assisted living.

In this clause a set of already identified medical applications using UWB technologies will be presented. The goal of these presentations will be the identification of the key requirements and features of the applications. Furthermore, the operational environment for the specific application will be identified and analysed in order to understand the potential interference behaviour and the corresponding mitigation factors.

5.2.2 Wireless Video Transmission in Operating rooms

5.2.2.1 Introduction

A typical operating room or intensive care environment in a hospital has several video systems that are in use and need to be connected either with diagnostic equipment or video servers. Some examples of equipment to be connected to a video screen are systems for endoscopic investigations or video signals during a surgery.

The use of wireless video streaming based on UWB will bring the following main advantages compared to wired connections:

- Wireless systems improve efficiency:
  - Facilitate faster turn-around time of ORs through reduced down-time from wires getting disconnected and shorter cleaning time between procedures.
- Improves Safety:
  - Eliminates a safety hazard due to long cables laying in the OR during procedures.
- Improves mobility and flexibility:
  - Allows flexible equipment layouts.
- Wireless video connectivity reduces costs of system installations.
- The very low TX power of the UWB devices will significantly reduce the interference risk to sensitive equipment.
- Robust against typical narrowband interferers.
- No typical interferers in the environment.
- Interferers like WiFi or Bluetooth are in different frequency ranges.

In figure 1 a typical setup in an OR equipped with UWB based video screens is depicted.

Figure 1: Typical setup of an operating room equipped with video screens using UWB-based wireless video

The wireless streaming system in the OR environment needs to be able to support up to three independent streams with a very high resolution. The interference potential towards the OR equipment should be as small as possible in order to limit the risk of a malfunction due to emissions of the streaming system.

5.2.2.2 System requirements

The basic system requirements can be summarized as follows:

- Three independent channels.
- Non interruptible streaming operation (no DAA or LDC).
- Range: 10 m to 20 m.
- Data rate: 480 Mbit/s to 1 Gbit/s.
- Video compression.
- Low latency.
- Low TX power for reduced interference risk to equipment.
- Low interference probability from other systems like WLAN or Bluetooth.

5.2.2.3 Technical description

The typical technical parameters of a medical imaging streaming system using UWB is given in table 1. The example system works in the lower UWB frequency band (3,1 GHz to 4,8 GHz with a mean e.i.r.p. of up to -41,3 dBm/MHz) and is designed to cover a range of up to 10 m. Future systems will operate in the band 6 GHz to 8,5 GHz but with a limited range due to the mean e.i.r.p. of -41,3 dBm/MHz. In order to guarantee the same range like in the lower band, the power would need to be increased to at least -31,3 dBm/MHz.

For the presented application scenarios in an operating room or an intensive care environment the additional mitigation factors (controlled and shielded environment) could be used to increase in TX power in the order of 10 dB without an increase in the interference potential in the band 6 GHz to 8,5 GHz towards the relevant victim systems.

Table 1: Example technical parameters of a typical UWB based streaming system for OR applications in hospitals

System Parameter	Value/Description
Signal Type	Ultra Wide Band (UWB)
Frequency Range	3,1 GHz - 4,8 GHz or 6 GHz to 9 GHz
Transmit Power (mean EIRP)	-41,3 dBm/MHz (mean power) in the band 3,1 GHz - 4,8 GHz -31,3 dBm/MHz (mean power) in the band 6,0 GHz - 8,5 GHz
Channel Bandwidth	528/1 056/1 584 MHz for FFI/TFI-2/TFI-3 channels
Data Rates	53,3 Mbps - 1 000 Mbps
Tx to Rx Range	Up to 20 m
Antenna Diversity	Two antenna diversity at receiver
Power Control	Dynamic transmit power calibration and up to 15 dB power back off
Video Compression	H.264
System Latency	< 1 Video Frame
Input Power	10 to 26 V DC
Power Consumption	14 W (Max)
Bonding of Tx/Rx Pair	Memory-Enabled Pairing System

5.2.2.4 Mitigation factors

In this clause the main identified mitigation factors will be presented. These mitigation factors will be used in conjunction with the potential interference and coexistence investigations.

For the wireless video streaming application in the OR environment the following main mitigation factors have been identified:

- Fully controlled environment:
  - Professional installation and maintenance.
  - Access control.
  - Fully shielded operating room for interference protection:
    - Significantly higher indoor-to-outdoor attenuation.
- Only strong NLoS conditions towards potential victim systems.
- No other radio services allowed in close vicinity, i.e. BWA, radar, 3G, LTE, etc.
- 100 % indoor deployment.
- Power controlled UWB system (12 dB dynamic).
- Bi directional system with limited activity in the downlink (< 10 %), uplink can be up to 90 %.

5.2.3 UWB based cardio-pulmonary sensor for animals

5.2.3.1 Introduction

An example of a UWB health monitoring application is a device that collects cardio-pulmonary data from animals via UWB radar integrated into an animal collar. This physiological data is transmitted via WiFi or Bluetooth to a cloud-based application, enabling pet owners and veterinarians to monitor the health and behaviour of their animals. Better data allows earlier intervention and better recovery, improving the quality of life and potentially prolonging life.

Similar to traditional radar, the UWB transceiver in the animal collar emits a series of extremely short duration pulses (~1 nanosecond) of electromagnetic energy. When these pulses propagate into the animal's body, the anatomical structures in their path are illuminated by the RF energy. As a result of the differences in dielectric properties, some of the incident energy is reflected back to the sensor at tissue discontinuities and boundaries. The reflected energy is analysed to extract useful physiological information. The pulse shape results in a UWB frequency spectrum that is extremely broadband with low average power, enabling examination of close-in targets and providing extremely fine radial resolution and motion detection.

Analysing the type, location, size, and relative movement of the illuminated tissues and organs via UWB radar enables quick, easy and safe measurements of advanced physiological functions without requiring skin contact, conductive gels, electrodes, or leads. More common health monitoring technologies (ECG, SpO2) ultrasound, bio-impedance, etc.) require direct skin contact. Animal fur prohibits the use of these technologies, while behaviour and environmental conditions also make these technologies impractical for animal applications. UWB radar transceivers, which are relatively inexpensive and can be easily miniaturized, can penetrate fur and detect microscopic motions of internal structures. They can also be sealed in a hard plastic case, making them resistant to physical damage and adverse environmental conditions.

Given these significant advantages over traditional methods for monitoring the health of animals, the use of UWB radar stands to revolutionize not only how pets are cared for, but also how non-companion animals, such as production livestock and pharmaceutical test animals, are raised. For example, most animals are currently monitored only through visual clues, which emerge too late in the progression of a disease to provide veterinarians with sufficient notice. A typical usage of the collar is depicted in figure 2.

Figure 2: Animal Collar with UWB-based Radar for Physiological Monitoring

5.2.3.2 System requirements

The UWB animal collar operates in the 3,1 GHz - 4,8 GHz band. Access to these low frequencies is critical for the successful operation of UWB medical radar applications. Empirical tests have shown that on-body UWB medical radar operation above 6 GHz produces little, if any, useable physiological data in animals or humans, while a narrower operating band limits both near-field interrogation and resolution, therefore also limiting the efficacy of the measurement results. It is therefore important for UWB health monitoring applications to have access to a wide frequency band below 6 GHz to operate effectively. The basic technical parameters are given in table 2.

Table 2: Technical parameters for animal sensor

System Parameter	Value/Description
Signal Type	Ultra Wide Band (UWB)
Frequency Range	3,1 GHz - 4,8 GHz (frequencies down to 2,2 GHz would be beneficial)
Average Transmit Power	TX power = 0,16 mW = -8 dBm mean TX power = -41,3 dBm/MHz (see note)
Channel Bandwidth	1,7 GHz
Data Rates	N/A
Tx to Rx Range	6,4 ns (14 cm typical in the body based on Er(tissue) = 50)
Antenna Diversity	Two antenna diversity at receiver - one TX antenna and one RX antenna
Power Control	N/A
Video Compression	N/A
System Latency	N/A
Input Power	3,7 V DC
Power Consumption	1 W (Max)
Bonding of Tx/Rx Pair	One TX/RX pair per UWB radar transceiver
NOTE: TX power will not be radiated into the free space. External limits below -50 dBm/MHz, see also ETSI EN 302 065-4 [i.5].	

5.2.3.3 Technical description

Due to the increased RF energy absorption by biological tissue with increasing frequency, it is critical that the transmitted spectrum of health and wellness devices based on UWB radar be as low as possible to generate usable physiological data.

The UWB animal sensor, licensed for operation in the United States, produces a transmitted signal with a spectrum where the 10 dB bandwidth is between 3,1 GHz - 4,8 GHz. Access to spectrum in the lower range of these frequencies is critical for the successful operation of UWB medical radar applications to minimize SNR degradation due to tissue absorption of the RF energy.

The UWB radar animal sensor consists of three key sections - a timing circuit, a transmitter, and a receiver. The timing circuit synchronizes the transmitter and receiver, allowing the radar to collect data at various depths within the neck of an animal. The timing circuit produces two related timing signals that are separated by a precise difference - one controlling the UWB transmitter and one controlling the UWB receiver. The difference corresponds to the time of flight from the transmitter to the target of interest and back to the receiver. Each rising edge in the transmitter's timing signal causes the transmitter to generate an impulse that propagates into the animal's neck. Similarly, each rising edge in the receiver's timing signal causes the receiver to sample the reflections.

The UWB transmitter uses a step recovery diode to generate a series of impulses that propagate into the neck. Each impulse is a bipolar monocycle that is approximately 3 Volts peak-to-peak where the positive half-cycle has a pulse width of less than 100 ps. A diplexer at the output of the impulse generator helps minimize lower frequency emissions. The high frequency leg of the diplexer is connected to the transmit antenna.

The UWB receiver samples and down converts the reflections emanating from the animal's neck. The receiver consists of four sections - an impulse generator, a sample and hold, a series of low frequency gain and anti-alias filter blocks, and an analog-to-digital converter. As in the transmitter, the receiver impulse generator creates a series of impulses. Each impulse is a unipolar monocycle that is approximately 1,5 Volts peak-to-peak where the positive-only cycle has a pulse width of less than 150 ps. Each receiver impulse triggers a sample and hold that samples, filters, and down converts the reflections incident on the receive antenna. The down-converted signal is averaged, amplified, and filtered by the LF channel to increase signal strength and limit signal bandwidth. The ADC converts the amplified and filtered LF analogue signal to 16 bit digital values for signal processing by the embedded microcontroller.

The UWB transmitter and receiver have separate antennas. Each antenna is a two-sided planar geometry fabricated directly on the FR-4 printed circuit board. The antenna design is based on a single feed elliptical geometry modified to efficiently transfer energy when loaded by biological tissue. The structure has a return loss less than -10 dB for frequencies between 3,1 GHz - 8 GHz.

Next generation UWB animal sensor

The UWB radar circuitry being incorporated into the next generation collar is based on the integrated chip. This chip is a fully integrated transceiver for UWB Impulse Radar applications. The basic components are a transmitter, a receiver and related control circuits. The receiver is tightly integrated with the transmitter and is designed for coherent integration of the received energy. The system is configurable through a 4-wire Serial Peripheral Interface.

The receive path (RX) in the chip consists of a Low Noise Amplifier (LNA), a Digital-to-Analog Converter (DAC), a 256 tap delay line, 256 Analog-to-Digital Converters (ADC), and 256 32-bit digital integrators, as well as an output memory buffer, accessible through the SPI. A radar frame consists of a single sweep from the minimum range to the maximum range, stepping through all range bins sequentially. In the chip, a RX bin is composed of the combination of a DAC and integrator where the bin is connected to one tap of the delay line and triggered by a delayed version of the RX clock.

The transmit path (TX) of the chip consists of a pulse generator capable of generating pulses at a rate of up to 100 MHz. Each pulse consists of a sinusoid modulated by a Gaussian window. The output frequency can be measured and adjusted over a large frequency range to allow spectral tuning to aid in meeting both application needs and regulatory requirements.

The timing of the RX and TX paths is individually adjustable through two sets of parallel delay lines. The relative difference in timing between the RX and TX path defines the time of flight from the transmitter, to the target of interest, and back to the receiver.

5.2.3.4 Mitigation factors

The primary physiological data collected by the UWB animal sensor consists of resting heart and respiratory rates. This data is obtained by interrogating an animal's neck with the UWB radar integrated into the collar while the animal is resting. This technology allows non-invasive monitoring of vital signs without requiring direct skin contact and with minimal obstruction from hair, but the animal is required to be at rest to minimize external noise and reduce physiological variability. Animals that are moving or walking introduce noise into the UWB signal, decreasing the ability to accurately and reliably measure vital signs. External stimulation and activity introduce heart rate and respiratory variability, minimizing the medical relevance of the data. A timer and an accelerometer determine when the animal is at rest so the UWB radar can be enabled. The UWB radar for consumers is active for a maximum of 3 consecutive minutes per day, typically in the middle of the night, resulting in an low activity factor. The clinical version of the UWB radar is active for a maximum of 3 minutes every hour. For both applications, the UWB transmitter operates at a maximum duty cycle of 10 %. The vast majority of energy from the UWB radar is absorbed by the animal's body. Calculations and measurements show that the transmitted energy is reduced by around 20 dB due to tissue absorption based on 3cm depth and a frequency of 3 GHz [i.19]. Absorption losses are larger for increased frequencies. The corresponding measurement setup and limits in ETSI EN 302 065-4 [i.5] takes these effects into account by defining a measurement based on a scenario.

In summary the following mitigation factors can be assumed for the application:

- Very low activity factor for the consumer device as compared to devices described in ETSI TR 103 181-1 [i.17], clause 4.2.4 (material sensing devices), one measurement per day of 3 minutes → 0,2 % activity factor.
- Same activity factor for clinical use as for devices described in ETSI TR 103 181-1 [i.17], clause 4.2.4 (material sensing devices), up to 3 minutes per hour, 5 %.
- Duty cycle restricted to 10 % maximum.
- Transmission directed into absorbing material, emission levels outside of the measurement scenario are below -50 dBm/MHz e.i.r.p. as described in ETSI TR 103 181-1 [i.17], clause 4.2.4.
- Directed emissions with high rejection in other directions.
- Operation only if in close proximity to the measurement object.
- LBT or DAA for the protection of applications in the band below 3,4 GHz, see ETSI TR 103 181-2 [i.18], clause 5.1 (listen-before-talk).
- For devices without LBT or DAA below 3,4 GHz a duty cycle restriction could be implemented.

5.2.4 UWB health monitoring application

5.2.4.1 Introduction

An example of a UWB health monitoring application is a fetal monitoring system. Fetal monitoring systems and applications based on UWB are expected to improve delivery outcomes and lower the cost of care to help healthcare institutions meet their cost reduction goals. In addition, such a system can improve the experience of labour and childbirth for both clinicians and expectant mothers. A new solution is urgently required as the current care standard is increasingly ineffective with higher risk populations. The monitor is expected to improve upon signal accuracy and reliability in the majority of expectant mothers as compared to existing non-invasive monitors. In addition, there is the opportunity to introduce new features such as fetal movement, fetal respiration, multigestational monitoring, and placental abruption, all of which are valued by clinicians.

Like traditional radar, the fetal monitoring UWB transceiver emits a series of extremely short duration pulses (~70 picoseconds) of electromagnetic energy. When these pulses propagate into the mother's body, the anatomical structures in their path are subjected to the RF energy. As a result of the differences in dielectric properties of the underlying tissues and organs, some of the incident energy is reflected back to the sensor at tissue discontinuities and boundaries. The reflected energy is analysed to extract useful physiological information. The specific pulse characteristics result in a transmitted frequency spectrum that is extremely broadband with low average power, enabling examination of close-in targets and providing extremely fine radial resolution.

Analysing the type, location, size, and relative movement of the tissues and organs via UWB radar enables quick, easy and safe measurement of advanced physiological functions without requiring skin contact, conductive gels, electrodes, or leads. More commonly used medical monitoring technologies (ECG, SpO2, ultrasound, bio-impedance, etc.) require direct skin contact.

Given these significant advantages over traditional methods for monitoring maternal fetal health, the use of UWB radar stands to revolutionize maternal fetal care in both the 3rd trimester as well as during labour and delivery.

5.2.4.2 System requirements

The fetal monitoring transceiver operates in the 3,1 GHz - 8,0 GHz band. Access to these low frequencies is critical for the successful operation of UWB medical radar applications, lower frequencies would even be more beneficial. Empirical tests have shown that UWB medical radar operation above 6 GHz produces little, if any, useable physiological data in humans, while a narrower operating band limits both near-field interrogation and resolution, therefore also limiting the efficacy of the measurement results. It is therefore important for UWB health monitoring applications to have access to a wide frequency band below 6 GHz and even below 3,1 GHz to operate effectively.

Table 3: Technical parameter health monitor application

System Parameter	Value/Description
Signal Type	Ultra Wide Band (UWB)
Frequency Range	3,1 GHz - 8,0 GHz lower frequencies down to 2,2 GHz would improve the performance significantly
TX Power	0,221 mW/-7 dBm in 5 GHz into human body, mean TX power = -41,3 dBm/MHz (see note)
Channel Bandwidth	4,9 GHz
Data Rates	N/A
Tx to Rx Range	7 ns (15 cm typical in the body based on Er(tissue) = 50)
Antenna Diversity	Two antenna diversity at receiver - one TX antenna and one RX antenna
Power Control	N/A
Video Compression	N/A
System Latency	N/A
Input Power	10 to 26 V DC
Power Consumption	1 W (Max)
Bonding of Tx/Rx Pair	One TX/RX pair per UWB radar transceiver
NOTE: TX power will not be radiated into the free space. External limits below -50 dBm/MHz, see also ETSI EN 302 065-4 [i.5].	

5.2.4.3 Technical description

The basic technical operations of a fetal monitoring system is similar to the cardio-pulmonary sensor for animals descript in clause 5.2.3.3.

5.2.4.4 Mitigation factors

The primary physiological data collected by a fetal monitoring system is uterine contractions and fetal heart rate. This data is obtained by interrogating the mother's abdomen with the UWB radar. External stimulation and activity introduce assessed signal variability, minimizing the medical relevance of the data. The vast majority of energy from the UWB radar is absorbed by the mother's body. Calculations and measurements show that the transmitted energy is reduced by around 20 dB due to tissue absorption based on 3 cm depth and a frequency of 3 GHz [i.19]. Absorption losses are larger for higher frequencies.

In summary the following mitigation factors can be assumed for the application:

- Very low activity factor for the consumer device as compared to devices described in ETSI TR 103 181-1 [i.17], clause 4.2.4 (material sensing devices), one measurement per day of 3 minutes → 0,2 % activity factor.
- Higher activity factor for clinical use under full professional control in a controlled environment.

- Transmission directed into absorbing material, emission levels outside of the measurement scenario are below -50 dBm/MHz e.i.r.p. as descript in ETSI TR 103 181-1 [i.17], clause 4.2.4 and in ETSI EN 302 065-4 [i.5].
- Directed emissions with high rejection in other directions.
- Operation only if in close proximity to the measurement object.
- LBT or DAA for the protection of applications in the band below 3,4 GHz, see ETSI TR 103 181-2 [i.18], clause 5.1 (listen-before-talk).
- For devices without LBT or DAA below 3,4 GHz a duty cycle restriction could be implemented.
- Duty cycle restricted to 10 % maximum during measurements.

5.2.5 UWB based on-body medical radar

5.2.5.1 Introduction

Cardiovascular diseases (CVD) are the leading causes of death and disability in the world. In the EU, the costs for CVD inpatient care was nearly 100 billion Euro in 2009. Persons affected by Congestive Heart Failure is estimated to increase to more than 20 million in Europe by the year 2020. The UWB based medical radar addresses unmet needs in a large market with disruptive innovative technology implemented in a novel and cost-effective device. UWB radar based products may be used by both heart specialists, physicians, and patients, and the number of potential users are estimated to be several million.

The primary objective is a new medical device that can be used by patients with CardioVascular Diseases (CVD) to perform cardiac self-monitoring anywhere and anytime. The device is based on Ultra Wide Band- Radar technology, and enables monitoring of global heart function (left and right ventricle function), heart rate variability and congestive heart failure (pulmonary fluid). The monitored data from individual recordings will be transferred to a central database for comparison with the patient's heart baseline data, and controlled and assessed by a cardiac specialist. In addition the monitoring data can be transferred to an app on a smart phone for use by patients.

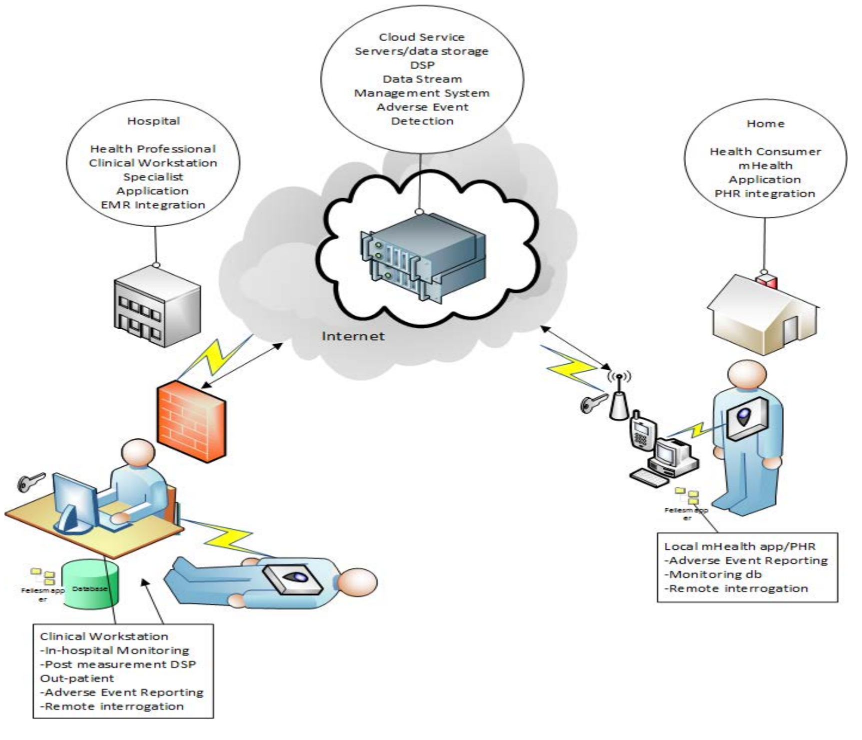

Figure 3: UWB based assisted living devices

5.2.5.2 System requirements

The human body is a very good attenuator for high frequency signals, where even only a few centimetres will reduce the signal power dramatically. In order to achieve sufficient SNR, access to frequencies below 6,0 GHz is of critical importance. Testing has been performed with prototypes operating from 3,1 GHz - 4,4 GHz and with prototypes in the 6,0 GHz - 8,5 GHz range. The preliminary results show that the higher frequency version does not provide sufficient SNR for application-level processing of heart mechanical movements. From an interference point of view towards the UWB device the best operational band would be 2,7 GHz to 3,4 GHz. In this band only radar systems are operational which can be detected.

Table 4: Technical parameters of UWB based radar applications

System Parameter	Value/Description
Signal Type	Ultra Wide Band (UWB)
Frequency Range	3,1 GHz - 4,4 GHz (see note 1)
Transmit Power	0,5 mW = -3 dBm (into material) (see note 2)
Channel Bandwidth	1,3 GHz
Data Rates	N/A
Tx to Rx Range	5 ns (10 cm typical in the body based on Er(tissue) = 50)
Antenna Diversity	Two antenna diversity at receiver - one TX antenna and one RX antenna
Input Power	5 V DC
Power Consumption	750 mW
Bonding of Tx/Rx Pair	One TX/RX pair per UWB radar transceiver
NOTE 1: From interference point of view the best operational band would be 2,7 GHz to 3,4 GHz. In this band only radar systems are operational which can be detected. NOTE 2: TX power will not be radiated into the free space. External limits below -50 dBm/MHz, see also ETSI EN 302 065-4 [i.5].	

5.2.5.3 Technical description

The medical sensor module is based on a dedicated CMOS UWB radar sensor SoC performing the actual sensing and high speed sampling/digitization of raw sensor data. The data is transferred to an MCU for post-processing which further interfaces through either a USB or wireless link to a host platform performing application-level signal processing and data analysis. The very high sample-rate of the system (40 GS/s) corresponds to very fine time-resolution enabling advanced application level processing to detect specific signs or indications of abnormal function. Since the sensor data is based on actual mechanical movement or physical conditions, many diseases may be discovered at an earlier stage compared to techniques like an ECG analysis.

5.2.5.4 Mitigation factors

The main target measurement for the UWB medical radar sensor is heart and lung related parameters. Thus the sensor is placed onto the body with antennas adapted for maximum signal transfer into the tissue, with minimal leakage to the exterior. Calculations and measurements show that the transmitted energy is reduced by around 20 dB due to tissue absorption based on 3 cm depth and a frequency of 3 GHz [i.19]. Absorption losses are larger for higher frequencies.

In summary the following mitigation factors can be assumed for the application:

- Very low activity factor for the consumer device as compared to devices described in ETSI TR 103 181-1 [i.17], clause 4.2.4 (material sensing devices), one measurement per day of 3 minutes equals to 0,2 % activity factor.
- Higher activity factor for clinical use under full professional control in a controlled environment.
- Transmission directed into absorbing material, emission levels outside of the measurement scenario are below -50 dBm/MHz e.i.r.p. as descript in ETSI TR 103 181-1 [i.17], clause 4.2.4.
- Directed emissions with high rejection in other direction then the direction of measurement.
- Operation only if in close proximity to the measurement object.

- LBT for the protection of applications in the band below 3,4 GHz, see ETSI TR 103 181-2 [i.18], clause 5.1 (listen-before-talk).
- For devices without LBT below 3,4 GHz a duty cycle restriction could be implemented.
- Duty cycle restricted to 10 % maximum during measurements.
- Only strong NLoS conditions towards potential victim systems.

5.2.6 UWB based remote respiration and heart rate monitor

5.2.6.1 Introduction

Monitoring vital signs, such as blood pressure, pulse rate and respiration rate, are important components of patient care and can be done in a medical setting or even at home. Respiration rate, heart rate and heart rate variability are vital signs that can actually provide insight into one's general state of health and can also be a valuable indicator of underlying medical conditions.

In today's health market a shift from treatment to proactive monitoring with an abundant amount of self-tracking and monitoring devices available can be seen. As people are becoming more and more aware of their health and are taking the extra measures to stay healthy, these convenient products can help them monitor their state of health throughout the day.

UWB based sensor technology offers a good compromise between penetration capabilities and range/angular resolution due to the large bandwidth and proper wavelength. These fundamental properties enable robust sensing of vital signs in complex environments ranging from line-of-sight to more complex situations where the sensor may be embedded into chairs, beds, etc.

Some applications are listed below:

- In-patient monitoring inside bed.
- Healthcare supervision.
- Sudden infant death syndrome (SIDS).
- In-car driver monitoring heartbeat for drowsiness detection including out-of-positioning monitoring [i.19].

The applications can be implemented using either contact or contactless based sensors (see clause above). The requirements given in this clause are based on contactless applications.

5.2.6.2 System requirements

The current product operates in the generic 3,1 GHz - 8,5 GHz band and offers robust sensing of respiration and heart rate up to 8 m and 4 m respectively in a line-of-sight environment. To enable good performance in more complex scenarios where line-of-sight cannot be assumed the benefit of increasing the allowable frequency range downwards is obvious due to the improved penetration capabilities.

Table 5: Technical parameter UWB based remote respiration and heart rate monitor

System Parameter	Value/Description
Signal Type	Ultra Wide Band (UWB)
Frequency Range	3,1 GHz - 8,5 GHz (see note)
Transmit Power (mean power)	0,04 mW = -14 dBm -> PSD = -50 dBm/MHz
Channel Bandwidth	5,4GHz
Data Rates	N/A
Tx to Rx Range	10 cm to 5 m (From sensor to object)
Antenna Diversity	Two antenna diversity at receiver - one TX antenna and one RX antenna
Input Power	3,3 V DC
Power Consumption	300 mW (Max)
Bonding of Tx/Rx Pair	One TX/RX pair per UWB radar transceiver
NOTE: Lower frequencies down to 2,2 GHz would improve the performance.	

5.2.6.3 Technical description

The respiration/heart rate sensor is based on a small size autonomous UWB radar module consisting of a CMOS UWB SoC and one pair of TX/RX antennas embedded into the module PCB substrate.

The UWB CMOS SoC contains all components needed to perform radar operation and outputs direct RF sampled or downconverted raw time-domain digital data which is transferred to the MCU for application level signal processing. It consists of RF TX/RX front-ends, A/D converters, digital core logic, necessary I/O, and power management.

The sensor operation is based on transmitting very short higher-order Gaussian pulses with high PRF from the TX antenna towards the human. The reflected pulses are sampled with a very high sampling rate (> 20 GS/s). From the sampled data respiration and heart rate are extracted from the mechanical movement of the chest corresponding to time-of-flight variations. Since the radar sensor is fully coherent both velocity and range are measured with high accuracy. Pulse-Doppler processing is performed by the MCU which also calculates the actual rates and exports time-domain respiration and heart traces for visualization or further processing.

The sensor has separate transmit and receive antennas. Each antenna is a multi-layer planar geometry fabricated on the PCB substrate. The antenna is a rectangular patch geometry with return loss less than -10 dB for the target frequency range.

5.2.6.4 Mitigation factors

The target use of this equipment is in controlled environments like hospitals and in doctor offices. The main mitigation technique is thus the indoor to outdoor attenuation of the transmitted energy.

In summary the following mitigation factors can be assumed for the application:

- Antenna patterns with strong directivity, mainly down tilt.
- Low duty cycle < 2 %.
- Typical activity factor 8 hours per day.
- Mainly indoor use cases.
- Quasi fixed installation.
- Controlled environments.

5.3 Classification of medical sensor UWB applications

5.3.1 General

Medical UWB applications were historically proposed for heart monitoring. The underlining idea was that to detect the movements of the heart wall by UWB radar tracking. Although many authors were able to obtain a heart-movement-related signal out of an UWB radar, a convincing model is still lacking.

5.3.2 Non imaging applications (or mode-B echography)

5.3.2.1 Cardiology and vascular

In these applications the movement of the wall of the heart or vessel is monitored to detect heart rate. If the signal of the UWB radar has a reasonable fidelity with the displacement of the heart or vessel, more data can be obtained like the time of arrival of the pulse pressure wave in the vessel tree or heart muscle velocity (a measure which might be correlated with heart failure). The possibility to simultaneously follow the movements of the two left ventricle walls (the one in contact with the thorax and that on the other side) might open the possibility to perform an estimation of the ejection fraction (supposing a suitable geometrical model of the left ventricle can be established). But this possibility yet seems more science fiction that reality. Another (science-fiction-like) application was proposed by analysing the morphology (or frequency content) of the returned echo in relation to the emitted pulse. It was postulated that this analysis might open the way for an electromagnetic tissue characterization of the heart.

5.3.2.2 Pulmonary

UWB radar systems can be used to detect breath rate. As a matter of fact in this case it suffices to detect thorax movement without even penetrating the body. UWB tissue characterization might also be possible.

5.3.2.3 Ear-Nose-Throat medicine

UWB radar systems were initially proposed for vocal cord detection in the aim of obtaining a sort of electromagnetic microphone to be used in noisy environments. Although no actual application was ever published, nevertheless UWB radar vocal cord monitoring has been done for diagnostic of vocal cord disease.

The study of glottis movements by UWB radar might also be considered to investigate swallowing diseases.

5.3.2.4 Gastroenterology

Movement of bowels and other visceral organs are good candidates for monitoring with UWB radar system.

5.3.2.5 Midwifery

Foetus's movements, foetus's heart rate and uterine contractions was considered for monitoring using UWB radar systems. Unlike ultrasound and pressure sensors the UWB radar might be placed at a distance from the patent so the caregivers would have full access to assist in the delivery.

5.3.3 Imaging applications

5.3.3.1 Introduction

Real imaging applications of UWB radar were never presented, nevertheless imaging-like applications for detection and monitoring of body parts and objects not in motion are listed here.

5.3.3.2 Trauma and cerebral vascular care

A few authors attempted to propose UWB radar monitoring of the head for detection of trauma or haemorrhage. This led to proposing UWB radar as a fast and effective system for rapid diagnosis in cases of trauma medicine like the battle field.

5.3.3.3 Oncology

Application of UWB radar in oncology was proposed as a means for detecting UWB scattering or absorption disturbances which might be indicative of a tumour, mostly in the field of breast tumours.

5.3.3.4 UWB radar scanner

A proper UWB radar scanner to reconstruct a slice of the human body by using attenuation or scattering properties of the body has been proposed but never realized.

6 Current regulations

6.1 Overview

The existing regulation framework for UWB in Europe already covers a broad range of possible application areas. Originally it was planned to have only a generic regulation for all UWB applications. Due to the multitude of different applications and related mitigation factors this approach was only partly efficient. In recent years several specific application related regulations have emerged to cover these specifics. Most of the relevant regulations are covered in Commission Decision 2014/702/EU [i.9]. In decision 5 different applications are mentioned and regulated in separate annexes beside the generic use case. In this clause the focus is on the regulations which are relevant for the depicted medical use cases only.

6.2 Generic regulation

The generic regulation for communication and other devices in the band 3,1 GHz to 4,8 GHz and 6 GHz to 9 GHz is summarized in table 6.

Table 6: Limits for generic UWB devices in EC Decision 2014/702/EU [i.9] and ECC/DEC/(06)04 [i.6]

Frequency range	Maximum mean e.i.r.p. spectral density	Maximum peak e.i.r.p. (defined in 50 MHz)
Below 1,6 GHz	-90 dBm/MHz	-50 dBm
1,6 to 2,7 GHz	-85 dBm/MHz	-45 dBm
2,7 to 3,4 GHz (see notes 1 and 2)	-70 dBm/MHz	-36 dBm
3,4 to 3,8 GHz (see notes 1 and 2)	-80 dBm/MHz	-40 dBm
3,8 to 4,2 GHz (see notes 1 and 2)	-70 dBm/MHz	-30 dBm
4,2 to 4,8 GHz (see notes 1 and 2)	-70 dBm/MHz	-30 dBm
4,8 to 6 GHz	-70 dBm/MHz	-30 dBm
6 to 8,5 GHz	-41,3 dBm/MHz	0 dBm
8,5 to 10,6 GHz (see note 2)	-65 dBm/MHz	-25 dBm
Above 10,6 GHz	-85 dBm/MHz	-45 dBm
NOTE 1: Within the band 3,1 - 4,8 GHz, devices implementing **Low Duty Cycle (LDC) mitigation technique** (see annex 2 in [i.9]) are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz. NOTE 2: Within the bands 3,1 - 4,8 GHz and 8,5 - 9 GHz, devices implementing **Detect And Avoid (DAA) mitigation technique** (see annex 3 in [i.9]) are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.		

The main challenges in the generic regulations for the medical applications in the present document are listed below:

- Mitigation like DAA (detect and avoid) and LDC (low duty cycle) are necessary; DAA could be critical for streaming applications, see use case for streaming in operating rooms. LDC cannot be deployed in high data rate streaming applications.
- In the 6 GHz - 8,5 GHz band a limit of -31,3 dBm/MHz would be needed for the range up to 10 m.
- No specific interior limits are given taking into account shielding and controlled environments.

6.3 Material sensing devices

The regulation for imaging and sensor application (Object Discrimination and Characterization, ODC) is covered in Annex 1 of ECC Decision (07)01 [i.10] and annex 5.1 of the EC decision 2014/702/EU [i.9]. This regulation is partly different from the generic regulation depicted in clause 6.2 of the present document. The operational band of UWB is extended down to 2,2 GHz taking into account specific mitigation factors like the absorption of the UWB signal in the material to be characterized. In some other bands the limits are more restrictive than in the generic case, e.g. in the band between 6 GHz to 8,5 GHz only -50 dBm/MHz is allowed. The regulatory parameters for material sensing UWB devices are given in table 7.

Table 7: Limits for material sensing UWB devices in EC Decision 2014/702/EU [i.9] and ECC/DEC/(07)01 [i.10]

Frequency range	Fixed installations (Application A)		Non fixed installations (Application B) Maximum mean e.i.r.p. spectral density
	Maximum mean e.i.r.p spectral density	Maximum mean e.i.r.p spectral density in the horizontal plane (-20° to 30° elevation)	
Below 1,73 GHz	-85 dBm/MHz		-85 dBm/MHz
1,73 to 2,2 GHz	-65 dBm/MHz	-70 dBm /MHz	-70 dBm/MHz
2,2 to 2,5 GHz	-50 dBm/MHz		-50 dBm/MHz
2,5 to 2,69 GHz	-65 dBm/MHz Note 1	-70 dBm/MHz	-65 dBm/MHz See notes 1 and 2
2,69 to 2,7 GHz	-55 dBm/MHz	-75 dBm/MHz	-70 dBm/MHz See note 3
2,7 to 2,9 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz
2,9 to 3,4 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz See note 1
3,4 to 3,8 GHz	-50 dBm/MHz	-70 dBm/MHz	-50 dBm/MHz See notes 2 and 3
3,8 to 4,8 GHz	-50 dBm/MHz		-50 dBm/MHz
4,8 to 5 GHz	-55 dBm/MHz	-75 dBm/MHz	-55 dBm/MHz See notes 2 and 3
5 to 5,25 GHz	-50 dBm/MHz		-50 dBm/MHz
5,25 to 5,35 GHz	-50 dBm/MHz	-60 dBm/MHz	-60 dBm/MHz
5,35 to 5,6 GHz	-50 dBm/MHz		-50 dBm/MHz
5,6 to 5,65 GHz	-50 dBm/MHz	-65 dBm/MHz	-65 dBm/MHz
5,65 to 5,725 GHz	-50 dBm/MHz	-60 dBm/MHz	-60 dBm/MHz
5,725 to 8,5 GHz	-50 dBm/MHz		-50 dBm/MHz
8,5 to 10,6 GHz	-65 dBm/MHz		-65 dBm/MHz
Above 10,6 GHz	-85 dBm/MHz		-85 dBm/MHz

NOTE 1: Devices using a Listen Before Talk (LBT) mechanism, as described in the harmonised standard ETSI EN 302 065-4 [i.5] which meet the technical requirements defined within appendix 1 to annex 1 of ECC/DEC(07)01 [i.10], are permitted to operate in frequency ranges 2,5 GHz to 2,69 GHz and 2,9 GHz to 3,4 GHz with a maximum mean e.i.r.p. spectral density of -50 dBm/MHz.

NOTE 2: To protect the radio services, non-fixed installations (application B) must fulfil the following requirement for Total Radiated Power:

a) In the frequency ranges 2,5 GHz to 2,69 GHz and 4,8 GHz to 5 GHz, the Total Radiated Power spectral density has to be 10 dB below the max e.i.r.p. spectral density.

b) In the frequency ranges 3,4 GHz to 3,8 GHz, the Total Radiated Power spectral density has to be 5 dB below the max e.i.r.p. spectral density.

NOTE 3: Limitation of the Duty Cycle to 10 % per second.

The main challenges in the material sensing regulations for the medical applications in the present document are listed below:

- In the 6 GHz - 8,5 GHz band a limit of -41,3 dBm/MHz would be beneficial.
- Above 8,5 GHz the limit should be like the generic limits, e.g. -65 dBm/MHz.

6.4 Building material analyses applications (BMA)

The regulation for BMA devices is covered annex 2 of ECC Decision (07)01 [i.10] and in annex 5.2 of the Commission Decision 2014/702/EU [i.9]. This regulation is partly different from the generic regulation depicted in clause 6.2 of the present document. The operational band of UWB is extended down to 2,2 GHz taking into account specific mitigation factors like the absorption of the UWB signal in the material to be characterized. In some other bands the limits are more restrictive than in the generic case, e.g. in the band between 6 GHz to 8,5 GHz only -50 dBm/MHz is allowed, in the band 8,5 GHz and 10,6 GHz only -85 dBm/MHz is allowed compared to -65 dBm/MHz in the generic case. The relevant regulatory limits are depicted in table 8.

Table 8: Limits for building material analysing UWB devices in EC Decision 2014/702/EU [i.9] and ECC/DEC/(07)01 [i.10]

Frequency range	Maximum mean e.i.r.p. spectral density
Below 1,73 GHz See note 1	-85 dBm/MHz
1,73 GHz to 2,2 GHz	-65 dBm/MHz
2,2 to 2,5 GHz	-50 dBm/MHz
2,5 GHz to 2,69 GHz See note 1	-65 dBm/MHz
2,69 GHz to 2,7 GHz See note 2	-55 dBm/MHz
2,7 GHz to 3,4 GHz See note 1	-70 dBm/MHz
3,4 GHz to 4,8 GHz	-50 dBm/MHz
4,8 GHz to 5 GHz See note 2	-55 dBm/MHz
5 GHz to 8,5 GHz	-50 dBm/MHz
Above 8,5 GHz	-85 dBm/MHz
NOTE 1: Devices using a Listen Before Talk (LBT) mechanism, as described in the harmonised standard ETSI EN 302 065-4 [i.5], which meets the technical requirements defined within Appendix 1 to Annex 1 of ECC/DEC(07)01 [i.10], are permitted to operate in frequency range 1,215 GHz to 1,73 GHz with a maximum mean e.i.r.p. spectral density of -70 dBm/MHz and in the frequency ranges 2,5 GHz to 2,69 GHz and 2,7 GHz to 3,4 GHz with a maximum mean e.i.r.p. spectral density of -50 dBm/MHz. NOTE 2: To protect the RAS bands 2,69 GHz to 2,7 GHz and 4,8 GHz to 5 GHz, the Total Radiated Power spectral density has to be below -65 dBm/MHz.	

The main challenges in the BMA regulations for the medical applications in the present document are listed below:

- In the 6 GHz - 8,5 GHz band a limit of -41,3 dBm/MHz would be beneficial.
- Above 8,5 GHz the limit should be like the generic limits, e.g. -65 dBm/MHz.

7 Proposed changes to regulation

Based on the requirements of the intended applications described in the present document, the following changes to the existing UWB regulation are proposed:

1) **Category A medical applications:** The proposal is to amend ECC Decision (06)04 for Communication Devices in controlled medical environments according to table 9.

2) **Category B medical applications:** The proposal is to amend ECC Decision (07)01 for contact based sensing and imaging devices according to table 10.

3) **Category C medical applications:** The proposal is to amend ECC Decision (07)01 for off-body/off-material sensing and imaging devices according to table 11.

Table 9: Proposed regulation for Communication Devices in controlled medical environments under professional use

	ECC/DEC(06)04 [i.6], annex 1	Proposal from ETSI TR 103 313
Frequency range	**Maximum mean e.i.r.p. spectral density**	**Communication Devices in controlled medical environments**
	Generic use; fixed outdoor and vehicle use excluded	Possible mitigations: • Indoor • Professional use • TPC 12 dB • Quasi fixed installation
Below 1,6 GHz	-90 dBm/MHz	-90 dBm/MHz
1,6 GHz to 2,7 GHz	-85 dBm/MHz	-85 dBm/MHz
2,7 GHz to 3,1 GHz	-70 dBm/MHz	-70 dBm/MHz
3,1 GHz to 3,4 GHz	-70 dBm/MHz (see notes 1 and 2)	-70 dBm/MHz (see note 3)
3,4 GHz to 3,8 GHz	-80 dBm/MHz (see notes 1 and 2)	-70 dBm/MHz (see note 3)
3,8 GHz to 4,2 GHz	-70 dBm/MHz (see notes 1 and 2)	-70 dBm/MHz (see note 3)
4,2 to 4,8 GHz	-70 dBm/MHz (see notes 1 and 2)	-70 dBm/MHz (see note 3)
4,8 GHz to 6 GHz	-70 dBm/MHz	-70 dBm/MHz (see note 3*)
6 GHz to 8,5 GHz	-41,3 dBm/MHz	-41,3 dBm/MHz (see note 4)
8,5 GHz to 9 GHz	-65 dBm/MHz (see note 2)	-65 dBm/MHz (see note 2*)
9 GHz to 10,6 GHz	-65 dBm/MHz	-65 dBm/MHz
Above 10,6 GHz	-85 dBm/MHz	-85 dBm/MHz

NOTE 1: Within the band 3,1 GHz - 4,8 GHz, devices implementing **Low Duty Cycle (LDC) mitigation technique** are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

NOTE 2: Within the bands 3,1 GHz - 4,8 GHz and 8,5 GHz - 9 GHz, devices implementing **Detect And Avoid (DAA) mitigation technique** are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

NOTE 2*: Within the band 8,5 GHz - 9 GHz devices operated in shielded and controlled medical environments are permitted to operate with a maximum mean e.i.r.p. spectral density of -31,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

NOTE 3: Within the band 3,1 GHz - 4,8 GHz devices operated in shielded and controlled medical environments are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

NOTE 3*: Within the band 4,8 GHz - 6,0 GHz devices operated in shielded and controlled medical environments are permitted to operate with a maximum mean e.i.r.p. spectral density of -55 dBm/MHz and a maximum peak e.i.r.p. of -15 dBm defined in 50 MHz.

NOTE 4: Within the band 6 GHz - 8,5 GHz devices operated in shielded and controlled medical environments are permitted to operate with a maximum mean e.i.r.p. spectral density of -31,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

Table 10: Proposed regulation for contact based sensing and imaging devices outside the measurement scenario (ETSI EN 302 065-4 [i.5])

	ECC/DEC(07)01 [i.10], annex 1				Proposal from ETSI TR 103 313
Frequency range	**Annex 1 ODC**			**Annex 2 BMA**	**Contact based sensing and imaging devices**
	Fixed and quasi fixed installation (Application A)		**Non fixed installations (Application B) Maximum mean e.i.r.p. spectral density**		**Possible mitigations:** • Indoor • [Professional use] • TPC 12 dB • exterior limits • TRP • Nobody only • LDC
	Maximum mean e.i.r.p spectral density	**Maximum mean e.i.r.p spectral density in the horizontal plane (-20 to 30° elevation)**			
Below 1,73 GHz	-85 dBm/MHz		-85 dBm/MHz	-85 dBm/MHz see note 1*	-85 dBm/MHz see note 1*
1,73 to 2,2 GHz	-65 dBm/MHz	-70 dBm/MHz	-65 dBm/MHz	-85 dBm/MHz	-65 dBm/MHz
2,2 to 2,5 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
2,5 to 2,69 GHz	-65 dBm/MHz Note 1	-70 dBm/MHz	-65 dBm/MHz (see notes 1 & 2)	-65 dBm/MHz (see note 1*)	-65 dBm/MHz (see note 1*)
2,69 to 2,7 GHz	-55 dBm/MHz	-75 dBm/MHz	-70 dBm/MHz (see note 3)	-55 dBm/MHz (see note 2*)	-55 dBm/MHz (see note 2*)
2,7 to 2,9 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz (see note 1*)	-70 dBm/MHz (see note 1*)
2,9 to 3,4 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz (see note 1)	-70 dBm/MHz (see note 1*)	-70 dBm/MHz (see note 1*)
3,4 to 3,8 GHz	-50 dBm/MHz	-70 dBm/MHz	-50 dBm/MHz (see notes 2 & 3)	-50 dBm/MHz	- 50 dBm/MHz (see notes 5 & 5*)
3,8 to 4,8 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	- 50 dBm/MHz (see notes 5 & 5*)
4,8 to 5,0 GHz	-55 dBm/MHz	-75 dBm/MHz	-55 dBm/MHz (see notes 2 & 3)	-55 dBm/MHz (see note 2*)	-55 dBm/MHz (see note 2*)
5,0 to 5,25 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,25 to 5,35 GHz	-50 dBm/MHz	-60 dBm/MHz	-60 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,35 to 5,6 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,6 to 5,65 GHz	-50 dBm/MHz	-65 dBm/MHz	-65 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,65 to 5,725 GHz	-50 dBm/MHz	-60 dBm/MHz	-60 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,725 to 6,0 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
6,0 to 8,5 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-41,3 dBm/MHz (see note 4)
8,5 to 9 GHz	-65 dBm/MHz		-65 dBm/MHz	-85 dBm/MHz	-65 dBm/MHz (see notes 5* and 4)
9 to 10,6 GHz	-65 dBm/MHz		-65 dBm/MHz	-85 dBm/MHz	-65 dBm/MHz
Above 10,6 GHz	-85 dBm/MHz		-85 dBm/MHz	-85 dBm/MHz	-85 dBm/MHz

<table>
<tr><th></th><th colspan="4">ECC/DEC(07)01 [i.10], annex 1</th><th>Proposal from ETSI TR 103 313</th></tr>
<tr><th>Frequency range</th><th colspan="3">Annex 1 ODC</th><th>Annex 2 BMA</th><th>Contact based sensing and imaging devices</th></tr>
<tr><td></td><td colspan="2">Fixed and quasi fixed installation (Application A)</td><td rowspan="2">Non fixed installations (Application B) Maximum mean e.i.r.p. spectral density</td><td rowspan="2"></td><td>Possible mitigations:
• Indoor
• [Professional use]
• TPC 12 dB
• exterior limits
• TRP
• Nobody only
• LDC</td></tr>
<tr><td></td><td>Maximum mean e.i.r.p spectral density</td><td>Maximum mean e.i.r.p spectral density in the horizontal plane (-20 to 30° elevation)</td><td></td></tr>
<tr><td colspan="6">NOTE 1: Devices using a Listen Before Talk (LBT) mechanism or other equivalent mechanisms, as described in the harmonised standard ETSI EN 302 065-4 [i.5], are permitted to operate in frequency ranges 2,5 GHz to 2,69 GHz and 2,9 GHz to 3,4 GHz with a maximum mean e.i.r.p. spectral density of -50 dBm/MHz.
NOTE 1*: Devices using a Listen Before Talk (LBT) mechanism or other equivalent mechanisms, as described in the harmonised standard ETSI EN 302 065-4 [i.5], are permitted to operate in frequency range 1,215 GHz to 1,73 GHz with a maximum mean e.i.r.p. spectral density of -70 dBm/MHz and in the frequency ranges 2,5 GHz to 2,69 GHz and 2,7 GHz to 3,4 GHz with a maximum mean e.i.r.p. spectral density of -50 dBm/MHz.
NOTE 2: To protect the radio services, non-fixed installations (application B) must fulfil the following requirement for Total Radiated Power:
a) In the frequency ranges 2,5 GHz to 2,69 GHz and 4,8 GHz to 5 GHz, the Total Radiated Power spectral density has to be 10 dB below the max e.i.r.p. spectral density.
b) In the frequency ranges 3,4 GHz to 3,8 GHz, the Total Radiated Power spectral density has to be 5 dB below the max e.i.r.p. spectral density.
NOTE 2*: To protect the RAS bands 2,69 GHz to 2,7 GHz and 4,8 GHz to 5 GHz, the Total Radiated Power spectral density has to be below -65 dBm/MHz.
NOTE 3: Limitation of the Duty Cycle to 10 % per second.
NOTE 4: No fixed outdoor permitted.
NOTE 5: Within the band 3,1 GHz - 4,8 GHz, devices implementing Low Duty Cycle (LDC) mitigation technique are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.
NOTE 5*: Within the bands 3,1 GHz - 4,8 GHz and 8,5 GHz - 9 GHz, devices implementing Detect And Avoid (DAA) mitigation technique are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.</td></tr>
</table>

Table 11: Proposed regulation for off-body/off-material sensing and imaging devices

	ECC/DEC(07)01 [i.10], annex 1				Proposal from ETSI TR 103 313
Frequency range	**Annex 1 ODC**			**Annex 2 BMA**	**off-body/off-material sensing and imaging devices**
	Fixed and quasi fixed installation (Application A)		**Non fixed installations (Application B) Maximum mean e.i.r.p. spectral density**		**Possible mitigations:** • Indoor only • Professional use • TPC 12 dB • exterior limits • TRP • LDC
	Maximum mean e.i.r.p spectral density	**Maximum mean e.i.r.p spectral density in the horizontal plane (-20 to 30° elevation)**			
Below 1,73 GHz	-85 dBm/MHz		-85 dBm/MHz	-85 dBm/MHz (see note 1*)	-85 dBm/MHz (see note 1*)
1,73 to 2,2 GHz	-65 dBm/MHz	-70 dBm/MHz	-65 dBm/MHz	-85 dBm/MHz	- 70 dBm/MHz
2,2 to 2,5 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
2,5 to 2,69 GHz	-65 dBm/MHz Note 1	-70 dBm/MHz	-65 dBm/MHz (see notes 1 & 2)	-65 dBm/MHz (see note 1*)	-65 dBm/MHz (see notes 1* & 2)
2,69 to 2,7 GHz	-55 dBm/MHz	-75 dBm/MHz	-70 dBm/MHz (see note 3)	-55 dBm/MHz (see note 2*)	-70 dBm/MHz (see notes 3 or 2*)
2,7 to 2,9 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz (see note 1*)	- 70 dBm/MHz (see note 1*)
2,9 to 3,1 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz (see note 1)	-70 dBm/MHz (see note 1*)	-70 dBm/MHz (see note 1*)
3,1 to 3,4 GHz	-50 dBm/MHz	-70 dBm/MHz	-70 dBm/MHz (see note 1)	-70 dBm/MHz (see note 1*)	- 70 dBm/MHz (see notes 1* or 5 or 5*)
3,4 to 3,8 GHz	-50 dBm/MHz	-70 dBm/MHz	-50 dBm/MHz (see notes 2 & 3)	-50 dBm/MHz	-50 dBm/MHz (see notes 5 or 5*)
3,8 to 4,8 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz (see notes 5 or 5*)
4,8 to 5,0 GHz	-55 dBm/MHz	-75 dBm/MHz	-55 dBm/MHz (see notes 2 & 3)	-55 dBm/MHz (see note 2*)	-55 dBm/MHz (see note 2*)
5,0 to 5,25 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,25 to 5,35 GHz	-50 dBm/MHz	-60 dBm/MHz	-60 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,35 to 5,6 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz
5,6 to 5,65 GHz	-50 dBm/MHz	-65 dBm/MHz	-65 dBm/MHz	-50 dBm/MHz	-65 dBm/MHz
5,65 to 5,725 GHz	-50 dBm/MHz	-60 dBm/MHz	-60 dBm/MHz	-50 dBm/MHz	-60 dBm/MHz
5,725 to 6,0 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-55 dBm/MHz
6,0 to 8,5 GHz	-50 dBm/MHz		-50 dBm/MHz	-50 dBm/MHz	-50 dBm/MHz (see note 4)
8,5 to 9 GHz	-65 dBm/MHz		-65 dBm/MHz	-85 dBm/MHz	-65 dBm/MHz (see note 4)
9 to 10,6 GHz	-65 dBm/MHz		-65 dBm/MHz	-85 dBm/MHz	-65 dBm/MHz
Above 10,6 GHz	-85 dBm/MHz		-85 dBm/MHz	-85 dBm/MHz	-85 dBm/MHz

	ECC/DEC(07)01 [i.10], annex 1				Proposal from ETSI TR 103 313
Frequency range	**Annex 1 ODC**			**Annex 2 BMA**	**off-body/off-material sensing and imaging devices**
	Fixed and quasi fixed installation (Application A)		**Non fixed installations (Application B) Maximum mean e.i.r.p. spectral density**		**Possible mitigations:** • Indoor only • Professiona l use • TPC 12 dB • exterior limits • TRP • LDC
	Maximum mean e.i.r.p spectral density	**Maximum mean e.i.r.p spectral density in the horizontal plane (-20 to 30° elevation)**			

NOTE 1: Devices using a Listen Before Talk (LBT) mechanism or other equivalent mechanisms, as described in the harmonised standard ETSI EN 302 065-4 [i.5], are permitted to operate in frequency ranges 2,5 GHz to 2,69 GHz and 2,9 GHz to 3,4 GHz with a maximum mean e.i.r.p. spectral density of -50 dBm/MHz.

NOTE 1*: Devices using a Listen Before Talk (LBT) mechanism or other equivalent mechanisms, as described in the harmonised standard ETSI EN 302 065-4 [i.5], which meets the technical requirements defined within appendix 1 to this Annex, are permitted to operate in frequency range 1,215 GHz to 1,73 GHz with a maximum mean e.i.r.p. spectral density of -70 dBm/MHz and in the frequency ranges 2,5 GHz to 2,69 GHz and 2,7 GHz to 3,4 GHz with a maximum mean e.i.r.p. spectral density of -50 dBm/MHz.

NOTE 2: To protect the radio services, non-fixed installations (application B) must fulfil the following requirement for Total Radiated Power:

a) In the frequency ranges 2,5 GHz to 2,69 GHz and 4,8 GHz to 5 GHz, the Total Radiated Power spectral density has to be 10 dB below the max e.i.r.p. spectral density.
b) In the frequency ranges 3,4 GHz to 3,8 GHz, the Total Radiated Power spectral density has to be 5 dB below the max e.i.r.p. spectral density.

NOTE 2*: To protect the RAS bands 2,69 GHz to 2,7 GHz and 4,8 GHz to 5 GHz, the Total Radiated Power spectral density has to be below -65 dBm/MHz.

NOTE 3: Limitation of the Duty Cycle to 10 % per second.

NOTE 4: No fixed outdoor permitted.

NOTE 5: Within the band 3,1 GHz - 4,8 GHz, devices implementing Low Duty Cycle (LDC) mitigation technique are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

NOTE 5*: Within the bands 3,1 GHz - 4,8 GHz and 8,5 GHz - 9 GHz, devices implementing Detect And Avoid (DAA) mitigation technique are permitted to operate with a maximum mean e.i.r.p. spectral density of -41,3 dBm/MHz and a maximum peak e.i.r.p. of 0 dBm defined in 50 MHz.

8 Main conclusions

8.1 Business importance

From the medical world, there is huge interest and demand for UWB applications. Location tracking of personnel, equipment, and patients, is already being rolled out. The new applications enabled by the regulations proposed in the present document will allow to further exploit the key characteristics of UWB where traditional systems fail to provide adequate solutions.

The medical environment is a very important use case for UWB manufacturers and vendors. Due to the critical nature of the medical business, it is not as price sensitive as others. This allows manufacturers to develop the technology for specific applications while gaining knowledge that can later be used in other verticals.

Annex A: Market information

A.1 Range of applications

See clause 5 of the present document.

A.2 Market size and value

A.2.1 Introduction

UWB based medical devices as described in the present document can be used in a broad set of applications. There are a variety of use cases including, clinical, home and animal monitoring applications . A specific mentioning of these applications in the regulation and a moderate adaptation of the regulatory limits as propose in clause 7 of the present document will open up a large market potential with a significant benefit for the consumers. In the following clause some estimated market figures will be presented.

A.2.2 Market potential Medical communication devices based on UWB

The proposed wireless streaming application for medical imaging has the following market potential in Europe.

Medical Imaging Display Market Size in Europe.

In 2012:

- Revenue Forecast: $289,4 Million.
- CAGR from 2005 to 2012: 14,8 %.
- Germany 30,4 %, United Kingdom 24,1 %, Italy 19,4 %, Benelux 7,4 %.
- Out of the above Revenue about 70 % will be Surgical Displays.

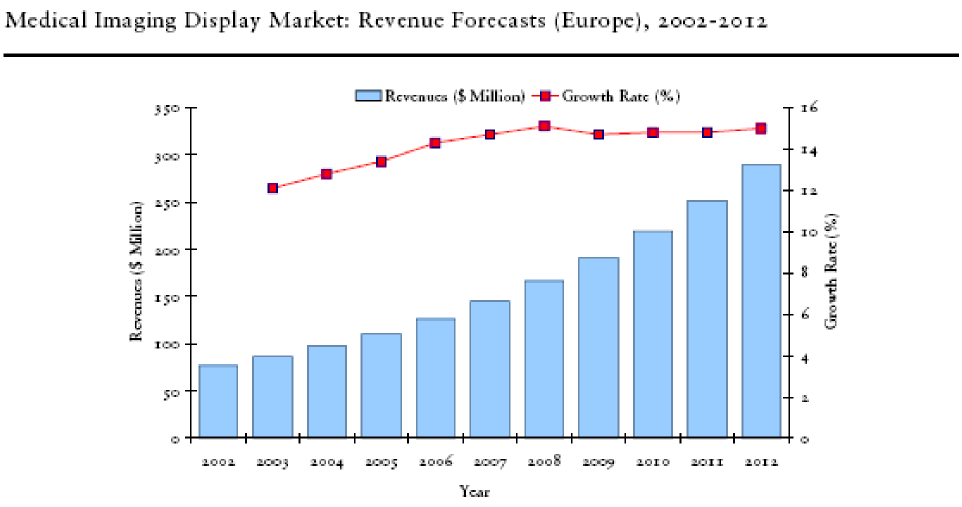

Figure A.1: Revenue forecasts medical imaging market 2002 - 2012

A.2.3 Market potential UWB based animal sensor device

The UWB based animal sensor device is intended as a consumer device for pet owners. However, clinical versions of the product for use by veterinarians are also under development. Distribution of animal sensor devices are expected via direct sales over the Internet, via veterinarian offices, and in some cases via retail stores. In the United States there are roughly 180 million dogs and cats, while within the European Union there are approximately 126 million.

Annex B: Technical information

See clause 5 of the present document.

Annex C: Expected compatibility issues

C.1 Existing Coexistence studies

In the scope of the UWB regulatory process a set of coexistence studies have been generated and published as ECC and CEPT reports:

- ECC Report 64 [i.13]: "The protection requirements of radio communications systems below 10,6 GHz from generic UWB applications".
- ECC Report 120 [i.11]: "ECC Report on Technical requirements for UWB DAA (Detect and avoid) devices to ensure the protection of radiolocation in the bands 3.1-3.4 GHz and 8.5-9 GHz and BWA terminals in the band 3.4-4.2 GHz".
- CEPT Report 34 [i.14]: "Report B from CEPT to European Commission in response to the Mandate 4 on Ultra-Wideband (UWB); Final Report on 30 October 2009 by the Electronic Communications Committee (ECC) within the European Conference of Postal and Telecommunications Administrations (CEPT)".
- CEPT report 45 [i.12]: "Report from CEPT to the European Commission in response to the Fifth Mandate to CEPT on ultra-wideband technology to clarify the technical parameters in view of a potential update of Commission Decision 2007/131/EC".
- ECC Report 94 [i.15]: "Technical requirements for UWB LDC devices to ensure the protection of FWA Systems".
- ECC Report 123 [i.16]: "The impact of Object Discrimination and Characterization (ODC) applications Using Ultra-Wideband (UWB) technology on radio services".
- ECC Report 251 [i.21]: "The impact of UWB applications on board aircraft in the band 6-8.5 GHz on FS links used around airports and on EESS earth stations", 2016.
- ECC Report 234 [i.22]:"Analyses of LDC UWB mitigation techniques with respect to incumbent radiocommunication services within the band 3.1 to 3.4 GHz", 2015.
- ECC Report 175 [i.23]: "Co-existence study considering UWB applications inside aircraft and existing radio services in 3.1-4.8 GHz/6.0-8.5 GHz", 2012.
- ECC Report 170 [i.24]: "Specific UWB applications in the bands 3.4 - 4.8 GHz and 6 - 8.5 GHz LAES, LT2 and LTA", 2011.

Annex D: Bibliography

- Andreuccetti 1997: D.Andreuccetti, R.Fossi and C.Petrucci: An Internet resource for the calcula-tion of the dielectric properties of body tissues in the frequency range 10 Hz - 100 GHz. IFAC-CNR, Florence (Italy), 1997. Based on data published by C.Gabriel et al. in 1996.

NOTE: Available at http://niremf.ifac.cnr.it/tissprop/.

- E. M. Staderini: "UWB radars in medicine", IEEE Aerospace and Electronic Systems Magazine 17.1 (2002): pp 13-18.
- J. Chang, C. Paulson, P. Welsh: "Development of Micropower Ultrawideband Impulse Radar Medical Diagnostic Systems for Continuous Monitoring Applications and Austere Environments", Lawrence Livermore National Laboratory. 978-1-4673-0658-4/12. IEEE 2012.
- R. Chávez-Santiago, I. Balasingham, and J. Bergsland: "Ultrawideband Technology in Medicine: A Survey", in Journal of Electrical and Computer Engineering, vol 2012, Article ID 716973, pp 9.
- A. Lazaro, D. Girbau, and R. Villarino: "Analysis of vital signs monitoring using an IR-UWB radar", Progress in Electromagnetics Research, vol. 100, pp. 265-284, 20100.
- O. Kosch, F. Thiel, B. Ittermann, and F. Seifert: "Non-contact cardiac gating with ultra-wideband radar sensors for high field MRI", in Proceedings of the 19th Annual International Society of Magnetic Resonance Medicine, pp 1804, May 2011.
- O. J. Babarinde, M. F. Jamlos, N. Bin Ramli: "UWB microwave imaging of the lungs: A review", in 2014 IEEE 2nd International Symposium on Telecommunication Technologies (ISTT), pp 188-193, November 2014.
- X. Li, S. K. Davis, S. C. Hagness, D.W.van der Weide, B.D.Van Veen: "Microwave imaging via space-time beamforming: experimental investigation of tumor detection in multilayer breast phantoms", in IEEE Transactions on Microwave Theory and Techniques, vol.52, issue 8, pg 1856-1865, 2004.
- M. Klemm, I. Craddock, J. Leendertz, A. Preece, R. Benjamin: "Experimental and clinical results of breast cancer detection using UWB microwave radar", in Antennas and Propagation Society International Symposium, 2008, AP-S 2008.
- M. Klemm, I. Craddock, J. Leendertz, A. Preece, D.R. Gibbins, M. Shere, R. Benjamin: "Clinical trials of a UWB imaging radar for breast cancer", in Proceedings of the Fourth European Conference on Antennas and Propagation.
- J.C.Y. Lai, C.B. Soh, E. Gunawan, K.S. Low: "UWB microwave imaging for breast cancer detections - experiments with heterogeneous breast phantoms", in Progress In Electromagnetics Research M, vol. 16, pg 19-29, 2011.
- E. Priidel, A. Mikola, R. Gordon, M. Martsepp, P. Kenkre, T. Taros, T. PärensonIn: "Bridging the Gap between Technology and Usability for Portable Brain Trauma Scanning Device", International Journal of Bioelectromagnetism, Vol.17, No.2, pp87-89, December 2015.

History

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