Coexistence of Wideband Ultra-Low Power Wireless Medical Capsule Endoscopy Application operating in the frequency band 430-440 MHz

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# Executive summary

This ECC report has been prepared to support any possible regulatory action to allow spectrum access for a new generation of professional medical Short Range Devices (SRD) application known as Ultra-Low Power Wireless Medical Capsule Endoscopy (WMCE).

The WMCE application is designed for professional use in medical doctor-patient scenarios with the aim of providing a convenient tool for diagnosis and treatment of human gastrointestinal (digestive) tract diseases. Its main benefit compared with colonoscopy tools traditionally used for this purpose is to offer an option of non-painful and non-invasive procedure with very low risk of bleeding or other side effects. WMCE application consists of two elements:

* a disposable miniature optical imaging camera implemented in the shape of a capsule - Capsule Camera (CCam), which is swallowed by the patient and transmits imaging data;
* a wearable Data Recorder (DR) placed on the patient to receive and store the imaging data transmitted by CCam.

Based on the analysis presented in this report, it may be concluded that the proposed WMCE application and specifically CCam transmitters operating in the frequency band 430-440 MHz would not create any significant risk of interference to other established users of the subject frequency range under most likely operational scenarios. This conclusion is made with reference to analysis based on Minimum Coupling Loss of the interference impact to radio amateur stations, radiolocation stations and other SRDs as reported in section 4.

Moreover, it appears highly unlikely that the proposed new application could be even detected beyond a few meters from the patient undergoing diagnostic procedure due to the combination of the following operational factors:

* the e.r.p. density of emissions measured outside patient's body (-50 dBm/100 kHz) would be significantly lower than the generally established spurious emissions limit of -36 dBm/100 kHz in the subject band;
* extremely low, compared with many other SRD applications, deployment density of WMCE and strictly limited duration of single-use disposable CCam devices for this very niche medical application;
* the fact that the patients would likely spend utmost time indoors, either in hospital or resting at homes during the diagnostic procedure, i.e. device operating time. Thus, it provides additional wall shielding with respect to other users of this band.

As regards of the interference in the other direction, there is a marginal risk of interference to DR receivers in case they happen to operate in direct proximity to high power stations in the subject band such as Amateur Radio or radiolocation. However, investigations show that presently the first generation of CCams very rarely experienced interference. Any rare occurrence of data loss is deemed acceptable for WMCE as non-life critical wireless communication. Since the density of both interferers and victims is very low, the probability for such interference occurrence is extremely low, and the risk is therefore marginal. However, it is up to a manufacturer to implement mitigation techniques such as digitally filtering of any in-band narrowband interferers in order to make the DR receiver even more robust for its intended use.

As overall conclusion, the above findings show a possible designation of the band 430-440 MHz as operating band for Ultra-Low Power WMCE application as feasible.

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LIST OF ABBREVIATIONS

| Abbreviation | Explanation |
| --- | --- |
| **C/I** | Carrier to Interference ratio |
| CCam | Capsule Camera, the transmitting part of WMCE application |
| CEPT | European Conference of Postal and Telecommunications Administrations |
| **CTCSS** | Continuous Tone-Coded Squelch System |
| **dB** | Decibel |
| **dBm** | Decibel relative to 1 mW |
| DR | Data Recorder, the receiving part of WMCE application |
| **ECC** | Electronic Communications Committee |
| **e.r.p.** | Effective Radiated Power |
| **ETSI** | European Telecommunications Standards Institute |
| **FSK** | Frequency-shift keying |
| **GFSK** | Gaussian Frequency-shift keying |
| IARU | International Amateur Radio Union |
| ISM | Industrial Scientific Medical |
| Mbps | Mega bit per second |
| **MCL** | Minimum Coupling Loss |
| **MSK** | Minimum-shift keying |
| **OFDM** | Orthogonal frequency-division multiplexing |
| **RF** | Radio Frequency  |
| **RX** | Receiver  |
| **SRD** | Short Range Device |
| **SRdoc** | System Reference document |
| **TX** | Transmitter  |
| **UHF** | Ultra-High Frequency |
| WMCE | Wireless Medical Capsule Endoscopy |
| **WG SE** | Working Group Spectrum Engineering |

# Introduction

The report has been prepared in response to ECC Working Group Spectrum Engineering (WG SE) in order to consider the ETSI System Reference Document TR 103 451 [1], which requested regulatory action to allow spectrum access for a new generation of professional medical Short Range Device (SRD) application termed Ultra-Low Power Wireless Medical Capsule Endoscopy (WMCE) and designed to be operated in UHF range around the 433 MHz. This new SRD application would be a valuable addition to diagnostic toolset of clinical professionals. It offers an opportunity of performing medical examination of patients with various gastrointestinal conditions without introducing the bleeding or sedation risks associated with colonoscopy, and therefore its use would be highly beneficial and attractive to both patients and doctors. The key part of the new application is a disposable miniature optical imaging camera implemented in the shape of a capsule, hence termed Capsule Camera (CCam) that is swallowed by the patient and transmits imaging data to a Data Recorder (DR) while moving through the patient's digestive system.

Currently, the globally harmonised ISM band covers the frequency band 433.05-434.79 MHz. In the ETSI System Reference Document (SRDoc) TR 103 451, the specific application of new generation of WMCE is however defined as operating in the frequency band 430-440MHz with a bandwidth up to 10 MHz.

The System Reference Document recommended designating for CCam transmissions a frequency band 430-440 MHz with maximum allowed e.r.p. of -40 dBm, measured outside patient's body. This report identifies the potentially affected incumbent radio-communication services in the subject band and looks at the compatibility issues involved with such regulatory action.

# Definitions

| Term |  | Definition |
| --- | --- | --- |
| Ultra-Low Power Wireless Medical Capsule Endoscopy |  | A Short Range Device application to be used for performing medical observation of human gastrointestinal tract by swallowing a Capsule Camera and receiving obtained images by external dedicated receiver, a Data Recorder |
| Capsule Camera |  | Miniature disposable capsule-shaped optical imaging camera with integrated Ultra-Low Power transmitter, a key element of Ultra-Low Power Wireless Medical Capsule Endoscopy Application |
| Data Recorder |  | Device worn by a patient in order to record the stream of images received from Capsule Camera and store it until it could be downloaded at the end of diagnostic procedure to doctor's Personal Computer for examination |

# Proposed New GENERATION OF WMCE Application

This section provides a short technical summary of the proposed new generation of existing application as distilled from full description provided in ETSI TR 103 451 [1]. The source reference may be further consulted for further technical details as well as clinical use specifics and provided market data as usually requested by CEPT ECC.

WMCE application is designed for professional use in medical doctor-patient scenarios with the aim of providing a convenient tool for diagnosis and treatment of human gastrointestinal (digestive) tract diseases. Its main benefit compared with colonoscopy tools traditionally used for this purpose is to offer an option of a non-painful and non-invasive procedure with very low risk of bleeding or other side effects. This is achieved by employing a miniature pill-shaped disposable CCam device intended for single use and having one or more built-in imaging sensors, which is activated by medical staff at the initiation of diagnostic procedure and then swallowed by a patient. Then, the CCam is naturally propelled through the patient's digestive system while transmitting internally obtained high resolution optical images through short range wireless connection to DR placed immediately outside patient's body (e.g. belt worn) as illustrated in the following Figure 1.

![C:\Users\amedeisis.c\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\F1XHZD2S\visceras[1].gif]()

435MHz

CCam

DR

Figure 1: Wireless Medical Capsule Endoscopy application scenario with CCam and DR

The Data Recorder (DR) may include an external antenna (possibly also with some active Radio Frequency (RF) front-end amplifier). It is to be placed directly on the patient's body by means of sticky pads or a designated belt worn around the waist, and it is to ensure reliable reception of weak signals from the operational CCam passing inside the patient's digestive tract.

The CCam should pass through the entire digestive tract within up to 12 hours, by which time its battery will be naturally depleted, and CCam will become inactive. By that time, the DR will also be removed from the patient's body, and the accumulated imaging data will be transferred through cable interface to some workstation for diagnostic analysis.

The activation and administration of CCam will always be done by medical staff in closed clinical environments (indoor use) and while the ambulatory patients may be then released for the duration of this painless and seamless procedure, as far as it is practical from a logistic and patient's physical condition view. This assumes that the initial portion of the procedure may be for short time outdoor in the case of patient's transfer from hospital to his home occurs.

It is therefore very likely that patients would spend most of the procedure time at rest in indoor environments such as at hospital or at home. From a radio-communication perspective, it is therefore correct to assume that a patient's CCam inspection session is utmost an indoor operation.

The above is further supported by the analysis of target medical market for WMCE applications explained by TR 103 451 [1]. Current forecasts suggest that the deployment density of active CCam transmitters in urban environments should not exceed 0.004 devices/km2 in the short term, and with long term market saturation limit estimated at 0.03 devices/km2.

The key technical parameters of CCam RF transmitter relevant for coexistence analysis are given in Table 1.

Table 1: Key RF parameters of CCam [1]

|  |  |
| --- | --- |
| Parameter | Value |
| Operating frequency band | 430-440 MHz |
| Occupied RF bandwidth (99%) | Single channel up to 10 MHz |
| Max e.r.p. of the CCam TX | -30 dBm |
| e.r.p. outside patient's body  | -40 dBm |
| Max e.r.p. density outside patient's body (TX mask limit) | -50 dBm/100 kHz |
| Duty Cycle | Up to 100% |
| Activity Cycle | Single use, up to 8-12 hours |

The e.r.p. values are consistent with ETSI TR 103 451 [1], once the body loss assumption of 10 dB is applied to differentiate the values inside/outside the body. It is to be noted that the last value is referring to power density, i.e. allowing for any unevenness of emissions over a very large channel bandwidth, and is therefore defined on a different, i.e. smaller, reference bandwidth of 100 kHz as opposed to total power defined for 10 MHz channel.

It should be noted that CCam emissions may not be very uniform across the entire 10 MHz channel bandwidth, so while the -40 dBm of total power as contained within the 10 MHz channel could be met. A 10 dB higher (-50 dBm) TX mask density limit is required over 100 kHz in order to give some more space for portions of the bandwidth that may have some higher power protrusions. Furthermore and most importantly for coexistence analysis, the -50 dBm/100 kHz TX mask density value was used as (conservative) reference maximum emission when evaluating its impact to other incumbent users of this band.

As regards spectrum access, it is assumed that CCam transmitters, may use direct access to radio channel with up to 100% DC and may use digital modulation such as MSK to transmit succession of still images during their activity period (i.e. during the diagnostic procedure). It was asserted in [1] that the size of a minimally acceptable quality image frame to provide sufficient resolution for medical diagnostic purposes is 256 rows × 256 columns × 8 bit/pixel = 512 Kbit. Practical tests showed that when the CCam moves rapidly through the human gastrointestinal tract (during a peristaltic wave) up to 20 images per second are required from one image sensor to get an adequate diagnostic coverage. This means that even in minimum resolution scenario the CCam will be generating a raw imaging bit stream of up to ~10 Mbps with one imaging sensor, or up to total of ~20 Mbps for CCam with 2 imaging sensors.

In order to reduce the required Radio Frequency (RF) transmission capacity and bandwidth as much possible, it was proven by initial design implementations that CCam electronics payload may carry out some essential image compression. It is also possible to vary the initial imaging bit stream by reducing the frame rate when the CCam moves slowly.

As stated in [1], it was reported that the minimum required bit rate in the uplink channel may be up to ~4 Mbps for CCam with one imaging sensor or up to ~8 Mbps when CCam employs two imaging sensors. If utilising MSK modulation this may result in up to 10 MHz of channel bandwidth.

# Coexistence Analysis

## Incumbent Services in the band

The target operating frequency band for CCam applications is 430 MHz to 440 MHz. The relevant provisions of ITU Radio Regulations' Article 5 [3] and European Common Allocations (ECA) [4] table are summarised in the following Table 2.

Table 2: Extract of ITU Radio Regulations and ECA for frequency range 430-440 MHz

| Frequency Band | ITU RR Allocations | ECA Allocations | ECA Applications |
| --- | --- | --- | --- |
| 430-432 MHz5.271, 5.274, 5.275, 5.277EU12 | RADIOLOCATIONAMATEUR | RADIOLOCATIONAMATEUR | Amateur |
| 432-433.05 MHz5.138, 5.271, 5.276, 5.277, 5.280EU12 | Earth Exploration-Satellite (active) (5.279A)AMATEURRADIOLOCATION | AMATEUREarth Exploration-Satellite (active) (5.279A)RADIOLOCATION | AmateurActive sensors (satellite) |
| 433.05-434.79 MHz5.138, 5.271, 5.276, 5.277, 5.280EU12 | RADIOLOCATIONAMATEUREarth Exploration-Satellite (active) (5.279A) | RADIOLOCATIONEarth Exploration-Satellite (active) (5.279A)Land MobileAMATEUR | Active sensors (satellite)Non-specific SRDsAmateurISM |
| 434.79-438 MHz5.138, 5.271, 5.276, 5.277, 5.280, 5.282EU12 | AMATEUREarth Exploration-Satellite (active) (5.279A)RADIOLOCATION | AMATEUR-SATELLITEEarth Exploration-Satellite (active) (5.279A)AMATEURRADIOLOCATION | Amateur-satelliteActive sensors (satellite)Amateur |
| 438-440 MHz5.271, 5.274, 5.275, 5.276, 5.277, 5.283EU12 | RADIOLOCATIONAMATEUR | RADIOLOCATIONAMATEUR | Amateur |

Based on the above summary of current ITU Radio Regulations and European common frequency allocations and use, it may be seen that the proposed use of Wideband Ultra-Low Power Wireless Medical Capsule Endoscopy application operating in the frequency band 430-440 MHz would mean band sharing with the following typical European radio-communication applications:

* Amateur Service;
* Earth Exploration-Satellite Service (active sensors);
* Non-specific SRDs.

Although it is not acknowledged in the ECA table as a typical application, there are known some installations of powerful radiolocation stations in at least two European countries, and they utilise primary service allocation in this band. The powerful signals from any such radiolocation stations may cause disruptions to the communication of very weak signals from CCam to DR. In the following sections, a review of the band sharing prospects with each of potentially affected applications is made.

It was also brought to the attention of this study that WMCE applications may occasionally suffer from unwanted emissions in cases of physical proximity to high power users of adjacent bands such as short-wave radio-communication stations or TETRA base stations. However as any such cases of adjacent band interference, the impact would be limited to the areas immediately adjacent to interfering stations. Evaluating any such residual risk from unwanted out-of-band emissions of services in adjacent bands would be entirely up to the manufacturers of WMCE equipment whom have to deal with such interference without requiring protection.

## Sharing with Amateur Service

As regards sharing between the proposed WMCE application and the Amateur and Amateur-Satellite services, it should be noted that the ITU-R Recommendation M.1044 [2] recommends that that the Amateur and Amateur-Satellite services may readily share with, inter alia, the Land Mobile services where traffic density is low.

Given that by their essence of operation at unidentified/changing locations the SRD applications such as WMCE are akin to mobile services and noting that in this case the CCam deployment and use density would be extremely low, and further shielded by buildings given highly unlikely occurrence of operating these two very different services in the same localities, the provisions of this ITU-R recommendation may be understood to implicitly endorse the sharing between the amateur/amateur-satellite services and the proposed WMCE application without requiring any further quantitative investigation.

In the course of this study, the International Amateur Radio Union (IARU) agreed with the above conclusion regarding interference to the Amateur Service from the CCam. However, the IARU also expressed opinion that some consideration needs to be given to the possibility of interference in the other direction. It could be i.e. to the DR receivers from stations in the Amateur Service but also, in certain geographical areas, from Radiolocation Service and Land Mobile Radio. The following band usage information and corresponding coexistence analysis address this issue.

Radio Amateur Transmissions existing in the band 430 to 440 MHz:

* Propagation beacons

Within the CEPT, there are 105 beacon transmitters operating on various frequencies between 431.999 MHz and 432.990 MHz, with e.r.p. ranging from 0.1 to 600 watts. These operate on a 100% duty cycle. The average e.r.p. from published information would appear to be about 25 watts, but with a very wide spread.

* Repeaters – Analogue and digital

In the UK alone, there are 320 repeaters with a wide geographical spread and e.r.p. of 25 watts, 64 repeaters linked to the internet and over 200 digital repeaters, and the numbers are growing. Because of interlinking, transmit duty cycles for the digital repeaters can reach levels as high as 80% during the day. Older analogue voice repeaters, even when not in active use, transmit information such as its call sign, location and often the CTCSS tone designation required for access at regular intervals between 5 and 15 minutes.

* Other Amateur use

Mobile stations with an e.r.p. of 50 watts can appear in a random manner: similarly fixed stations with an e.r.p. of 100 watts or more are not uncommon. Infrequently at weekends, there are competitions in which well-sited portable stations can be found using an e.r.p. up to 40kW from the use of high gain antennas.

* Non-Amateur Land Mobile Radio in the London area also uses frequencies in the band 430-432 MHz, and consideration needs to be given to the possibilities of interference from this service.

Co-existence of existing narrowband CCam operations with Radio Amateur use:

First generation of capsule endoscope devices operating at 433.92 MHz and using MSK modulation have been on the market for more than ten years, albeit with a narrower bandwidth than is proposed in the ETSI TR 103 451 [1]. So far, the vendors and users of those early CCam versions did not report any significant problems related to interference from other users of the band. It is to be noted that there was a complete session of five papers on the first generation of Capsule Endoscopy at the Conference on Electronics in Medicine and Biology held in Lyons, France, in August 2007.

However, it is difficult to draw a conclusion from the performance achieved from existing capsule endoscopes operating at 433 MHz with respect to interference from the Amateur Services. This is because the receiver bandwidth is less than 10 MHz, and so many of the transmissions in the Amateur Service, which might cause interference, are on frequencies outside the receiver bandwidth. This is no longer the case with a receiver having a 10MHz bandwidth, and any signal can be considered a potential interferer.

Analysis for DR as a victim:

As shown in Table 1, the CCam's e.r.p. outside the body will be -40dBm. The modulation to be used is not specified, but limitations in power and size suggests that for a 4Mbps data rate FSK, GFSK, GMSK or OFDM will be necessary. Assuming the minimum required C/I is 10dB (achievable with coherent detection), this means a maximum interfering signal level of -50 dBm for one interferer with a minimum coupling loss from a 25 watt signal of 94 dB. This equates to a free space interfering range of less than 1.7 km and when using the urban model with an exponent of 3.5, an interfering range of 17 m. This latter figure is probably optimistic over such a short range.

There is an inherent assumption that only one possible interferer exists which may well not be the case. Assuming the rare case of 4 nearby interferers of equal strengths, the interfering ranges become 3.4 km free space and 25 m for the urban model.

It should be noted that both beacons and repeaters are generally situated in elevated locations and can thus have a propagation exponent greater than 2 but less than the 3.5 used for true urban propagation prediction.

In conclusion, it is not possible to establish a definite probability of interference free operation because of the possible variations in radiated power and propagation. At the same time, it should be seen in the context of overall very low density of both WMCE use instances and Radio Amateur stations which makes their co-location in time and geographical locality a highly rare occurrence. Therefore, it may be reasonably asserted that the majority of WMCE users will not experience problems, although allowing uncontrolled ambulatory activity could lead to data loss in some rare situations. However, given that WMCE application is used solely for diagnostic purposes in non-real-time circumstances, any occasional data loss would just require repetition of the WMCE diagnostic procedure, perhaps in more controlled hospital environment if there is a suspicion that patient's home may be located near interference source that precludes reliable transfer of information between CCam and DR.

## Sharing with Earth-Exploration Satellite (EESS) Active Sensors

In accordance with the ITU RR footnote 5.279A, the active space-borne sensors (Synthetic Aperture Radars) within the Earth-Exploration Satellite (active) service may be used in accordance with provisions of ITU-R Recommendation RS.1260 on "Feasibility of sharing between active space-borne sensors and other services in the range 420-470 MHz" [5].

In order to safeguard operation of many other radio-communication services utilising frequency range 420-470 MHz this recommendation establishes that the Synthetic Aperture Radars may be operated only in short-term, infrequent and geographically targeted campaigns. This is in compliance with certain pfd limits established at the surface of the Earth and around certain more sensitive installations of, for instance, wind profiling radars.

It may be therefore reasonably assumed that the above provisions would also ensure implicit compatibility of active space-borne sensors with the proposed WMCE application, given its Ultra-Low Power emissions and especially thanks to additional mutual shielding provided by the buildings due to normal indoor location of patients with active CCams during diagnostic procedure.

## Sharing with Non-specific Short range devices (SRD)

According to CEPT ECC Recommendation ERC/REC 70-03 [6], non-specific Short Range Devices (SRDs) are allowed to operate in the frequency band 433.05-434.79 MHz. The following Table 3 summarises the key parameters of such Non-specific SRDs if they were considered spectrum sharing partners as potential victims of interference from CCam emissions.

Table 3: Parameters of considered victim Non-specific SRD receiver

| Parameter | Value |
| --- | --- |
| Operating frequency band | 433.05-434.79 MHz |
| Channel bandwidth | 25 kHz |
| Typical antenna gain | -2.85 dBi |
| Receiver sensitivity | -112 dBm/25 kHz |
| Target operational margin of wanted signal | 10 dB |
| C/I objective | 8 dB |

Using these key technical RF parameters of potential victim application vis-à-vis key CCam interfering transmitter parameters shown in Table 1, the coexistence with WMCE could be verified by applying Minimum Coupling Loss (MCL) calculation of maximum impact range, as shown in the following Table 4.

Table 4: MCL calculation of maximum impact range from CCam to Non-specific SRD victim receiver

| Parameter | # | Value | Remarks |
| --- | --- | --- | --- |
| Frequency, GHz | A | 0.43 |  |
| Interfering power, ERP, dBm | B | -50 |  |
| Reference bandwidth associated to "B" above, kHz | C | 100 |  |
| Victim RX bandwidth, kHz | D | 25 |  |
| Victim RX antenna gain, dBi | E | -2,85 |  |
| Victim RX sensitivity, dBm | F | -112 |  |
| Victim RX wanted signal margin, dB | G | 10 |  |
| Victim RX C/I objective, dB | H | 8 |  |
| Victim RX interference threshold, dBm | I | -110 | I=F+G-H |
| Bandwidth correction factor, dB | J | -6 | J=10\*LOG10(D/C) |
| Minimum Coupling Loss value, dB | MCL | 53.3 | MCL=B+2.15+J+E-I |
| Maximum impact range, m (urban, non-Line of Sight conditions) | Rnlos | 6 | Rnlos=POWER(10;(MCL-32.5-20\*LOG10(A))/35) |
| Maximum impact range, m (free space loss, Line of Sight conditions) | Rlos | 25 | Rlos=POWER(10;(MCL-32.5-20\*LOG10(A))/20) |

The methodology used in the above calculations is the standard Minimum Coupling Loss (MCL) methodology, and it allows establishing the maximum theoretical range at which the victim receiver can sense (detect) the emissions from interfering transmitter. The MCL method is appropriate tool for this task given the CCam's ultra-low emissions power outside patient's body which could only affect other spectrum users if they are in direct proximity to the patient undergoing the diagnostic procedure. This corresponds to "same room" interference scenario with Free Space Loss model used for path loss estimation.

The obtained MCL results show that within typical urban WMCE operating environment the maximum impact range is 6 m under worst case assumption of victim receiver operating at its sensitivity threshold. In most real situation, victim receivers will operate significantly above the sensitivity threshold which would reduce the effective impact range of WMCE interferer. And under the theoretically best propagation conditions (free space, line of sight), the WMCE impact range would be 25 m, which delineates the maximum theoretically possible detection range ceiling.

Considering these maximum realistic/theoretical impact ranges, it may be concluded that interference could only be possible if both WMCE and victim SRD are used essentially in the direct proximity such as within the same or adjacent room. This in turn means that any such interference would be occurring only in direct proximity of the patient undergoing diagnostic procedure and therefore any such intermittently observed interference could be clearly attributed to the fact of the diagnostic procedure taking place and therefore not cause any annoyances due to momentary disturbance of other SRDs used by patient. In cases when the patient would remain in the hospital ward for the duration of procedure, the hospital administration could prohibit use of 433 MHz SRD (in fact any wireless equipment, as is often the case in hospital wards with abundance of various sensitive medical equipment) at and near the locations of active WMCE procedures.

Therefore based on above considerations it may be finally concluded that operation of CCam would pose really negligible risk of interference to non-specific SRD uses in the band.

## Sharing with Radiolocation Service

As mentioned previously, this study received reports from at least two European countries that they have in operation radiolocation stations within the frequency band 420-450 MHz. The following Table 3 lists some of the key operational parameters of such stations, which correspond to the data recently used for study reported in ECC Report 240 [7] and the data provided in the ITU-R Recommendation M.1462 [8].

Table 3: Parameters of radiolocation stations in the band 420-450 MHz

|  |  |
| --- | --- |
| Parameters | Type of radiolocation station |
| Airborne | Ground |
| Bandwidth, MHz | 1 | 1  |
| Noise floor, dBm | -108.9  | -109.9  |
| Protection Criterion: I/N, dB | -6  | - 6  |
| Maximum Tolerable Interference, dBm | -114.9 | -115.9 |
| Antenna Gain within main lobe, dBi | 22 | 38  |
| Radar height above ground level, m | > 9000  | 8  |
| Polarisation | Circular | Circular |

The results of MCL calculation of maximum interference range from CCam to a victim radiolocation station are given in the Table 4 below.

Table 4: MCL calculation of maximum impact range from CCam to Radiolocation stations

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter | # | Value for airborne radar | Value for ground radar | Remarks |
| Frequency, GHz | A | 0.43 | 0.43 |  |
| Interfering power, ERP, dBm | B | -50 | -50 |  |
| Reference bandwidth associated to "B" above, kHz | C | 100 | 100 |  |
| Victim RX bandwidth, kHz | D | 1000 | 1000 |  |
| Victim RX antenna gain, dBi | E | 22 | 18 | For ground based radar, an average side-lobe attenuation of 20 dB is considered. |
| Victim RX interference threshold, dBm | I | -114.9 | -115.9 |  |
| Bandwidth correction factor, dB | J | 10 | 10 | J=10\*LOG10(D/C) |
| Minimum Coupling Loss value, dB | MCL | 99.05 | 96.05 | MCL=B+2.15+J+E-I |
| Maximum impact range, m (urban, non-Line of Sight conditions) | Rnlos | 129 | 105 | Rnlos=POWER(10;(MCL-32.5-20\*LOG10(A))/35) |
| Maximum impact range, m (free space loss, Line of Sight conditions) | Rlos | 4943 | 3460 | Rlos=POWER(10;(MCL-32.5-20\*LOG10(A))/20) |

For the airborne radar case, it should be noted that the maximum impact range does not exceed 4.9 km. As the airborne radars normally operate at altitudes higher than 9 km, it can be deduced that the CCam would not create harmful interference to airborne radars under the conditions and scenarios described above and noting the results in Table 4. Regarding the ground based radars, under the conditions and scenarios described above, noting the results in Table 4, and further considering a low deployment density of active CCam transmitters, it appears that the CCam use would pose negligible risk of interference to ground radars.

# Conclusions

Based on the analysis presented in this report, it may be concluded that it is highly improbable that the proposed use of WMCE application with CCam transmitter would cause significant risk of interferences to other established users of the subject frequency range.

Moreover, it appears highly unlikely that the proposed new application could be even detected beyond a few meters from the patient undergoing diagnostic procedure because of the combination of the following operational factors:

* the e.r.p. density of emissions measured outside patient's body (-50 dBm/100 kHz) would be significantly lower than the generally established spurious emissions limit of -36 dBm/100 kHz in the subject band;
* extremely low, compared with many other SRD applications, deployment density of WMCE and strictly limited duration of single-use disposable CCam devices for this very niche medical application;
* the fact that during the diagnostic procedure, i.e. device operating time, the patients would likely spend utmost time indoors, either in hospital or resting at homes, thus providing additional wall shielding with respect to other users of this band.

As regards the interference in the other direction, i.e. risk of interference to DR receiver, investigations show that presently used first generation of CCams very rarely experienced interference from radio amateur stations (or any other users such as a number of Radiolocation stations in a few European countries operating in the 430-440 MHz band). Those rare occurrences of data loss were deemed acceptable, this being non-life critical wireless communication. Since the density of both interferers and victims is very low, the probability for such interference occurrence is extremely low and the risk is therefore marginal. However, it is up to a manufacturer to implement mitigation techniques such as digitally filtering of any in-band narrowband interferers in order to make the DR receiver even more robust for its intended use.

1. List of References
2. ETSI TR 103 451 'System Reference document (SRdoc); Short Range Devices (SRD); Technical characteristics for UHF wideband Ultra-Low Power Wireless Medical Capsule Endoscopy' (2016)
3. ITU-R Recommendation M.1044-2 'Frequency sharing criteria in the amateur and amateur-satellite services' (June 2003)
4. ITU Radio Regulations' Article 5: <http://life.itu.int/radioclub/rr/art05.htm>
5. THE EUROPEAN TABLE OF FREQUENCY ALLOCATIONS AND APPLICATIONS IN THE FREQUENCY RANGE 8.3 kHz to 3000 GHz (ECA TABLE) (06/2016)
6. ITU-R Recommendation RS.1260-1 'Feasibility of sharing between active space-borne sensors and other services in the range 420-470 MHz' (May 2003)
7. CEPT ECC Recommendation ERC/REC 70-03 'Relating to the Use of Short Range Devices (SRD)' (amended February 2017)
8. ECC Report 240 'Compatibility studies regarding Broadband PPDR and other radio applications in 410-430 MHz and 450-470 MHz and adjacent bands' (September 2015)
9. ITU-R Recommendation M.1462 'Characteristics of and protection criteria for radars operating in the radiolocation service in the frequency range 420-450 MHz' (05/2000)