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Ultra Low Power Wireless Medical Capsule Endoscopy

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Contents

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Foreword

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

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

Modal verbs terminology

In the present document "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Executive summary

The present document describes the concept, technical details and operational scenario of novel professional medical Short Range Device application termed Ultra Low Power Wireless Medical Capsule Endoscopy application and designed to be operated in UHF range around the 433 MHz band. This new application would offer 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 patients and doctors. The key part of the new application is a disposable miniature optical imaging camera implemented in the shape of a capsule that is swallowed by the patient and transmits imaging data while moving through the digestive system.

The provided analysis recommends using the frequency band around 433 MHz band as the most optimal option, however the use of an up to 10 MHz wide channel with real-time imaging data does not fit into the existing European regulatory provisions for SRDs.

It is therefore proposed that the relevant annex 2 of the CEPT Recommendation ERC/REC 70-03 [i.1] is amended to include provisions for utilizing the proposed Ultra Low Power Wireless Medical Capsule Endoscopy application in the frequency band 430 MHz to 440 MHz with emitted power limit (e.r.p.) of -40 dBm outside patient's body.

1 Scope

The present document describes a new Short Range Device application in the form of Wideband Ultra Low Power Wireless Medical Capsule Endoscopy, to be deployed using one channel within UHF band, possibly around 433 MHz. Its proposed deployment in European market may require an amendment in the present CEPT regulatory framework for Short Range Devices in the proposed band regarding intended emissions of the new application.

The present document includes in particular:

- Use scenario for the proposed Wideband Ultra Low Power Medical Capsule Endoscopy devices.
- Market information.
- Technical information, including expected sharing and compatibility issues, if any.
- Regulatory considerations.

The present document is intended to provide all necessary information required by the Electronic Communications Committee (ECC) of CEPT under the MoU between ETSI and the ECC, to enable consideration of possible regulatory changes necessary to accommodate the proposed new application.

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] CEPT ECC Recommendation ERC/REC 70-03: "Relating to the Use of Short Range Devices (SRD)".

NOTE: Available at www.erodocdb.dk.

[i.2] ECO Frequency Information System EFIS.

NOTE: Available at www.efis.dk.

[i.3] Recommendation ITU-R RS.1260: "Feasibility of sharing between active spaceborne sensors and other services in the range 420-470 MHz".

[i.4] Recommendation ITU-R M.1044: "Frequency sharing criteria in the amateur and amateur-satellite services".

[i.5] ERC Recommendation 74-01: "Unwanted emissions in the spurious domain", Cardiff 2011.

NOTE: Available at www.erodocdb.dk.

[i.6] ETSI EG 201 788: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guidance for drafting an ETSI System Reference document (SRdoc)".

[i.7] ETSI EN 300 220-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Part 1: Technical characteristics and test methods".

[i.8] Final Acts - WRC-07.

NOTE: Available at http://www.itu.int/pub/R-ACT-WRC.8-2007.

[i.9] Final Acts - WRC-12.

NOTE: Available at http://www.itu.int/pub/R-ACT-WRC.9-2012/en.

[i.10] Final Acts - WRC-15.

NOTE: Available at http://www.itu.int/pub/R-ACT-WRC.12-2015.

3 Definitions and abbreviations

3.1 Definitions

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

Capsule Camera (CCam): miniature disposable capsule-shaped optical imaging camera with integrated ultra-low RF power SRD transmitter, a key element of Ultra Low Power Wireless Medical Capsule Endoscopy Application

channel: small frequency sub-band within the operating frequency band into which an intended radio signal fits

Data Recorder (DR): device worn by the patient in order to record the stream of images received from CCam and store it until it could be downloaded at the end of diagnostic procedure to doctor's PC for examination

duty cycle: ratio expressed as a percentage, of the total maximum transmitter "on" time on one carrier frequency, relative to a one hour period

NOTE: In accordance with CEPT Recommendation ERC/REC 70-03 [i.1].

Short Range Devices (SRDs): radio devices which provide either unidirectional or bi-directional communication and which have low capability of causing interference to other radio equipment and thus permitted to operate on non-protected/non-interference basis, normally under "license exempt" regulatory regime

ultra-low power wireless medical capsule endoscopy: type of SRD 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

3.2 Abbreviations

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

AMI	Active Medical Implant
CCam	Capsule Camera
CD	Crohn's Disease
CEPT	Conference Européenne des Postes et Télécommunications
CPU	Central Processing Unit
CRC	ColoRectal Cancer
CT	Computed Tomography
DC	Duty Cycle
DR	Data Recorder
e.r.p.	Effective radiated power
ECA	European Common (frequency) Allocations table, see CEPT ECC Report 25
ECC	Electronic Communications Committee of the CEPT
GI	GastroIntestinal
IBD	Inflammatory Bowel Disease

IDA	Iron Deficiency Anaemia
ISM	Industrial, Scientific, Medical frequency band
ITU	International Telecommunication Union
LED	Light Emitting Diode
MCL	Minimum Coupling Loss
MSK	Minimum Shift Keying (modulation type)
OGIB	Obscure GastroIntestinal Bleeding
PC	Personal Computer
Pfd	Power flux density
RF	Radio Frequency
RMS	Root Mean Square
RR	Radio Regulations
RX	Receiver
SAR	Synthetic Aperture Radars
SRD	Short-Range Device
TX	Transmitter
UC	Ulcerative Colitis
UHF	Ultra-High Frequency
USB	Universal Serial Bus

NOTE: A computer interface connector.

4 Comments on the System Reference Document

4.1 Statements by ETSI Members

Add here possible difficulties encountered (e.g. reservations on the present document and corresponding reasons). This clause should not be systematically filled; the aim is to provide to CEPT-ECC, as far as possible, a totally approved document, achieved as the result of a consensus between all ETSI members.

ETSI members are entitled to include a statement at this point in the present document, if their concerns cannot be included elsewhere. Such statements should be clearly attributable to the ETSI member(s) making these statements. However, members are encouraged to try to reflect alternative viewpoints within the body of the present document.

5 Presentation of the Wireless Medical Capsule Endoscopy system

Wireless Medical Capsule Endoscopy is a novel SRD application aimed at offering professional health care providers a range of innovative options for visualizing, diagnosing and monitoring the human Gastrointestinal (GI) tract, i.e. the digestive system.

The key part of this application is a medical SRD device, implemented as a miniature endoscope camera made in the shape of a capsule like a pharmaceutical pill. It is intended to be swallowed by the patient as any regular pill and then transmits optical images obtained while moving through the digestive system. Accordingly this device is here forth termed a Capsule Camera (CCam).

There may be different types of CCam, with one or more optical imaging sensors pointing in different directions, developed specifically for observations of different parts of human GI tract and different diagnostic objectives. Regardless of the diagnostic application type, all CCams are to share the same wireless uplink parameters, as they would use the same family of RF transmitters. It is envisaged that some types of CCam may also include a receiver for providing a control return channel through which the capsule's parameters may be ordered to change from time to time, e.g. enabling more tailored management of diagnostic data flow from the CCam. However such a control return channel may be realized using any of the available general purpose narrow-band SRD bands (e.g. at 13,56 MHz) and therefore is not the subject of the new technical requirements described in the present document.

The high level composition of CCam is shown in figure 1, while figure 2 provides an illustration of a real prototype device.

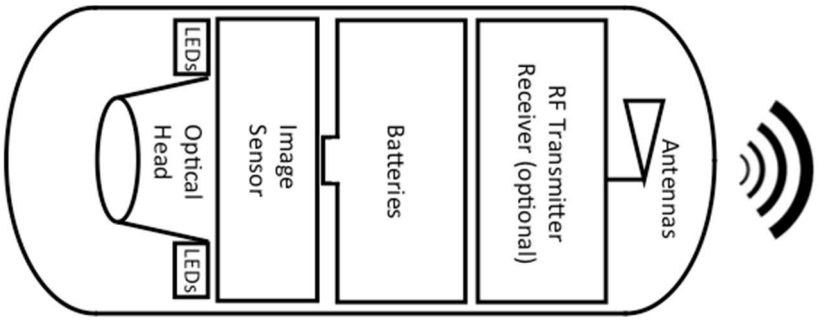

Figure 1: Block Diagram of CCam

Figure 2: Illustration of a practical CCam implementation (Image courtesy Given Imaging® Ltd)

Another essential part of the Wireless Medical Capsule Endoscopy system is the Data Recorder (DR). DR is a device placed on the outside of patient's body and carried by the patient during the entire capsule endoscopy procedure. The DR receives and demodulates the stream of images transmitted by the CCam, and stores it in an internal memory, see figure 3. DRs intended to be used with CCams utilizing a control return channel would naturally need also a narrowband transmitter to provide the required downlink functionality.

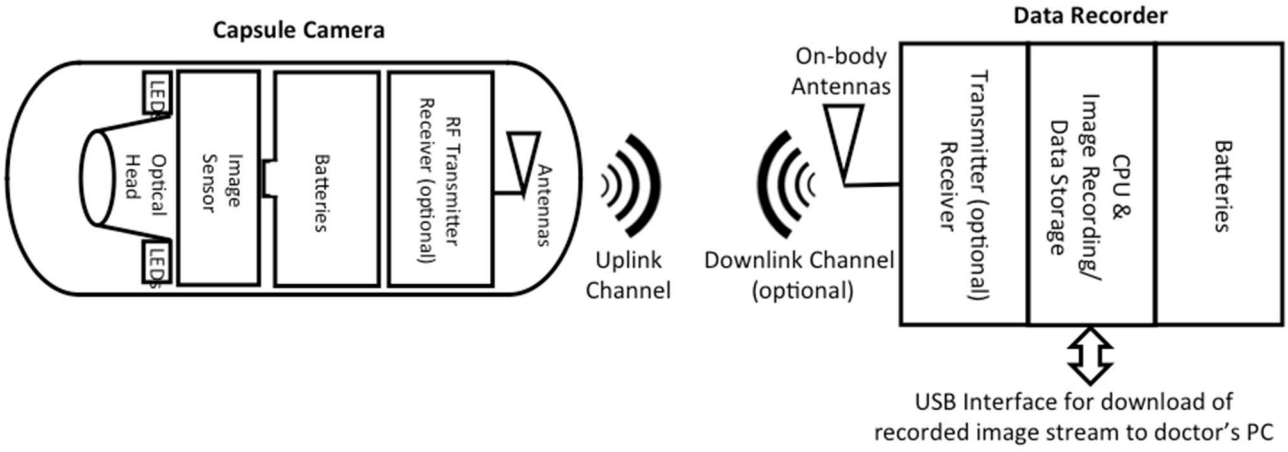

Figure 3: High-Level Block Diagram of proposed Wireless Medical Capsule Endoscopy system for GI diagnostic

The DR should be able to support various envisaged diagnostic types of CCams, and includes an external antenna (possibly with some RF front-end circuitry), which is placed directly on the patient's body by means of sticky pads or a designated belt worn around the waist, to ensure reliable reception of weak signals from the operational CCam passing inside the patient's GI tract.

A normal GI analysis procedure using CCam takes between 3 hours to 12 hours. Thus, both the CCam and DR are expected to work up to 12 hours consecutively, requiring radio circuits with superb power efficiency. Once the procedure is over, the DR is removed from the patient and connected via USB to a designated PC-based workstation. The images data acquired by the DR is then downloaded to a workstation for further processing and analysis by a specialist doctor.

Each CCam is a disposable device intended for one-time use. Once being activated, swallowed and after passing through the patient's GI tract it is disposed off with natural human waste while the full exhaustion of its batteries after intended operational period will implicitly render its electronic payload inactive, including full cessation of RF transmissions.

It is notable that the beginning and the conclusion of the procedure both take place in controlled hospital/ambulatory environments and while in the interim the patient may be temporarily released from the hospital, it is likely that he/she would spend most of the procedure time at rest in indoors environment such as at home.

6 Market information

When considering market for the proposed Wireless Medical Capsule Endoscopy application, it should be noted that this is a limited medical diagnostic application that are prescribed and administered in hospital and GI specialist clinics. Also notable is that this device is intended only for one-off limited-duration diagnostic procedure before the start of the treatment. This means that the number of device deployments will only grow initially while GI specialist doctors learn about the new product and familiarize with the new type of diagnostic procedure. Within a few years after market introduction the deployments of this device would reach the nominal equilibrium of targeted patient base related to growth/decline of the population with respect to either GI conditions or screening related procedures. More importantly, each such device deployment will have a very short duration and therefore there will be no aggregation of active devices in the overall populace. This is fundamentally different from many typical AMI applications, such as heart pacemakers, that are intended for actual long/indefinite-term treatment of patients.

The following calculations in table 1 show the predictions for possible long term market proliferation of the proposed Wireless Medical Capsule Endoscopy applications, based on current statistics of GI endoscopy procedures.

Table 1: Market forecast and deployment density of CCam

Parameter	Today	Long-term	Remarks
GI endoscopy procedures annually worldwide	300 000	1 500 000	Long term forecast of plateau demand after 10 years from market introduction
Europe as percentage of global market	20 %	30 %	
Procedures annually in Europe	60 000	450 000	
Procedures daily in Europe	300	2 250	Based on 200 work days/year
Number of clinics/hospital wards in Europe performing GI endoscopy	100	500	Growth thanks to relative simplicity of wireless endoscopy procedure
Procedures per day per clinic/ward	3	5	I.e. the maximum number of simultaneously active CCam in any urban "hot spot" i.e. near GI specialist hospital
Procedures per day per capita	4E-7	3E-6	Assuming European population 750 million
Number of procedures, i.e. effective density of CCam TX, per urban km^2	**0,004**	**0,03**	Assuming urban area with high population density of 10 000 persons/km^2

Some further details on various envisaged types of CCam and their respective medical market information is provided in annex A.

7 Technical information

7.1 Detailed technical description

7.1.1 Parameters of CCam

The CCam is a disposable device designed to be swallowed by patient and then acquire images during natural propulsion through the GI tract.

The main components of any capsule are (see figure 1):

- Plastic case in the shape of a pharmaceutical pill;
- Transparent optical head(s);
- Electronics payload, incl. RF transmitter, antennas, optical sensor(s), and LEDs (as light source);
- Batteries.

The proposed technical parameters of CCam are given in table 2.

Table 2: Proposed conceptual CCam specifications

CCam specifications	
Physical Dimensions	Length: 20 mm to 40 mm, Diameter: 10 mm to 15 mm
Operational imaging rate	Up to 20 frames/s (per imaging sensor)
Number of imaging sensors	1 or 2 initially, possibly more in the future
Operating time	Up to 12 hours
Wireless Uplink Communication Parameters	
Transmitter modulation signal type	Digital
Transmitter data rate	Up to 4 Mbps/sensor
Transmitter frequency band (proposed)	433 MHz
Occupied bandwidth (99 %)	Up to 10 MHz
e.r.p. (outside patient's body) measured with RMS detector	-40 dBm/10 MHz
Max e.r.p. of the CCam	-30 dBm/10 MHz

Note that regardless of diagnostic application type, all CCams would share the same wireless uplink parameters, as they use the same family of RF transmitters.

7.1.2 Parameters of Data Recorder

The DR is a battery operated, easily carried portable device, designed to be attached to the patient's belt during an entire duration of diagnostic procedure, in order to receive and store the digital images data transmitted by the CCam from within the patient's GI tract. After completion of the procedure, the DR is removed from patient's body and connected via wireline interface to a designated medical workstation, which downloads from DR the accumulated diagnostic imaging data for further processing.

Table 3 provides key technical parameters of DR receiver.

Table 3: Proposed conceptual DR uplink receiver specifications

Parameter	Value
Frequency band (proposed)	433 MHz
Channel bandwidth	Up to 10 MHz
Minimum sensitivity	-100 dBm to -80 dBm

To ensure the reliable reception of CCam signal, the DR is connected to external antenna, which is placed directly on the patient's body by means of sticky pads or a designated belt worn around the waist.

7.2 Technical parameters and implications on spectrum

7.2.1 Status of technical parameters

7.2.1.1 Current ITU and European Common Allocations

As explained in detail in clause 8 of the present document, the target operating frequency band for CCam applications is 430 MHz to 440 MHz. The relevant provisions of ITU Radio Regulations Article 5 and European Common Allocations Table are summarized in table 4 [i.2].

Table 4: Extract of ITU RR and ECA freqency allocations for the frequency range 430 MHz to 440 MHz

Frequency Band	ITU RR Allocations	ECA Allocations	ECA Applications
430 MHz to 432 MHz 5.271, 5.274, 5.275, 5.277 EU12	RADIOLOCATION AMATEUR	RADIOLOCATION AMATEUR	**Amateur**
432 MHz to 433,05 MHz 5.138, 5.271, 5.276, 5.277, 5.280 EU12	Earth Exploration-Satellite (active) (5.279A) AMATEUR RADIOLOCATION	AMATEUR Earth Exploration-Satellite (active) (5.279A) RADIOLOCATION	**Amateur** **Active sensors (satellite)**
433,05 MHz to 434,79 MHz 5.138, 5.271, 5.276, 5.277, 5.280 EU12	RADIOLOCATION AMATEUR Earth Exploration-Satellite (active) (5.279A)	RADIOLOCATION Earth Exploration-Satellite (active) (5.279A) Land Mobile AMATEUR	**Active sensors (satellite)** **Non-specific SRDs** **Amateur** **ISM**
434,79 MHz to 438 MHz 5.138, 5.271, 5.276, 5.277, 5.280, 5.282 EU12	AMATEUR Earth Exploration-Satellite (active) (5.279A) RADIOLOCATION	AMATEUR-SATELLITE Earth Exploration-Satellite (active) (5.279A) AMATEUR RADIOLOCATION	**Amateur-satellite** **Active sensors (satellite)** **Amateur**
438 MHz to 440 MHz 5.271, 5.274, 5.275, 5.276, 5.277, 5.283 EU12	RADIOLOCATION AMATEUR	RADIOLOCATION AMATEUR	**Amateur**

The explication of all ECA and ITU RR footnotes mentioned in table 4 are provided in annex B for reference purposes.

7.2.1.2 Sharing and compatibility studies already available

Based on the analysis of current ITU and CEPT frequency allocations as recited in clause 7.2.1.1 and annex B, it appears that the use of the proposed Wireless Medical Capsule Endoscopy application in the band 430 MHz to 440 MHz would mean sharing with the following typical European radiocommunication applications:

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

In accordance with ITU Radio Regulations footnote 5.279A [i.11], the active spaceborn sensors (Synthetic Aperture Radars - SAR) within the Earth-Exploration Satellite (active) service may be used in accordance with provisions of Recommendation ITU-R RS.1260 [i.3]. This recommendation establishes that in order to safeguard operation of many other radiocommunication services utilizing subject frequency range, the SARs may be operated only in short-term, infrequent and geographically targeted campaigns in compliance with certain pfd limits established at the surface of the Earth and around certain more sensitive installations of e.g. wind profiling radars.

It may be therefore reasonably assumed that the above provisions would also ensure implicitly compatibility of active spaceborn sensors with the proposed Wireless Medical Capsule Endoscopy application, given its ultra-low power emissions and especially thanks to additional mutual shielding afforded by the buildings due to normal indoor location of patients with active CCams during diagnostic procedure.

As relates to the sharing with the Amateur and Amateur-Satellite services, the Recommendation ITU-R M.1044 [i.4] 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 undefined place of operation the SRD applications 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 Wireless Medical Capsule Endoscopy application.

7.2.1.3 Sharing and compatibility issues still to be considered

As discussed in previous subsection, the compatibility of Wireless Medical Capsule Endoscopy application with Earth Exploration-Satellite (active) as well as Amateur/Amateur-Satellite service may be deemed assured based on previous relevant ITU-R studies. This leaves to consider the other potential sharing partner:

- Non-specific SRDs in frequency band 433,05 MHz to 434,79 MHz.

Table 5 summarizes the key parameters of two considered spectrum sharing partners as potential victims of interference from CCam emissions.

Table 5: Key RF parameters of considered victim radio system

Parameter	Non-specific SRD Rx (see note)
Operating frequency band, MHz	433,05 to 434,79
RX bandwidth, kHz	25
RX antenna gain, dBi	-2,85
RX sensitivity, dBm	-112
RX wanted signal margin, dB	10
C/I objective, dB	8
NOTE: Key SRD parameters collected from ERC/Recommendation 70-03 [i.1] (annex 1) and ongoing CEPT Project Team SE24, i.e. Work Item WI42-2.	

According to the above observations and provided key technical parameters of potential victim application, the additional compatibility check was done by applying MCL calculation of maximum impact range, as reported in annex C. It shows that the maximum impact range (i.e. the maximum range at which the victim could even detect presence of interfering transmitter, whereas the actual interference range should be normally even shorter because of victim normally having some operational margin for C/I worsening) is only between 3 and 8 m (8 m under line of sight), which means that interference could only be possible if both are used in the same room, and in direct proximity of patient and therefore any such occurrence of temporary interference could be implicitly understood by the patient as being due to his/her diagnostic procedure and therefore not cause any annoyances due to momentary disturbance of other SRDs used by patient. Naturally, when the patient would remain in the hospital ward for the duration of procedure, the hospital administration could easily ensure avoidance of using 433 MHz SRD in the facilities or at least near the CCam operations place.

Therefore based on MCL check provided in annex C and above considerations in this and previous sections it may be concluded that operation of CCam would pose really negligible risk of interference to other uses of the band.

7.2.2 Transmitter parameters

7.2.2.1 Transmitter Output Power / Radiated Power

As transpires from general technical description of CCam provided in clause 7.1.1, it will possess a very basic ultra-low power SRD transmitter constrained by the miniscule form-factor of enclosing capsule and very limited energy supply from button cell type battery. Furthermore it needs to be remembered that once activated and administered, i.e. swallowed by a patient, CCam's Tx will be operating only while the CCam moves inside the patient's body.

Therefore CCam Tx power is defined as maximum radiated power (e.r.p.) of -40 dBm/10 MHz, as measured at the outside surface of the patient's body (or outside human phantom body for compliance measurements).

7.2.2.2 Operating Frequency

As explained in detail in clause 8 of the present document, the frequency band 430 MHz to 440 MHz appears as the most reasonable compromise frequency band to be considered for CCam transmissions.

7.2.2.3 Bandwidth

As explained in detail in clause 8 of this document, the circumstances of CCam operational scenario lead to suggest that the minimum necessary bandwidth for CCam uplink signal will be up to 10 MHz, depending on the number of imaging sensors and speed of CCam passing through patient's GI tract.

It is therefore proposed to establish for uniformity purposes that the CCam transmissions will require occupied bandwidth of 10 MHz.

7.2.2.4 Unwanted emissions

It is notable that CEPT Recommendation ERC/Recommendation 74-01 [i.5] stipulates that SRD spurious emissions below 1 GHz should not generally exceed -36 dBm/100 kHz. However the wanted emissions power of ultra-low power CCam Tx constitutes just -40 dBm/10 MHz, or less than -50 dBm/100 kHz. This means that even the wanted signal of the CCam at source (i.e. just outside patient's body) will be well below general spurious emissions limits for SRDs. Accordingly the unwanted emissions would easily comply outside 430 MHz to 440 MHz with the spurious emission limits recommended by CEPT Recommendation ERC/ Recommendation 74-01 [i.5].

7.2.3 Receiver parameters

The receiver part of the Wireless Medical Capsule Endoscopy application will be implemented in the DR unit. As such it is less constrained in physical size and battery capacity than the transmitter inside the capsule. Therefore the DR receiver may be a typical state-of-the-art receiver with minimum sensitivity of -80 dBm/10 MHz (like Category 2 SRD as meant by ETSI EN 300 220-1 [i.7]).

All DR other receiver parameters are expected the same to general Category 2 receiver parameters established in ETSI EN 300 220-1 [i.7] applicable to generic Short Range Devices operating between 25 MHz and 1 GHz.

7.2.4 Channel access parameters

According to the operational scenario described in clause 5, the CCam transmitter have to be active and transmitting constantly the real-time image stream during the entire time of GI diagnostic procedure. The very limited signal processing capacity that may be realized in the CCam electronics payload, along with reliance on DR for storage of accumulated imaging data, means that even using digital signal processing techniques may not allow derivation of significant benefits in terms of reduction of necessary Duty Cycle of CCam transmissions. For the same reasons the CCam may not employ any selective channel access mechanism other than direct transmission within the only available channel.

This means that CCam TX needs to be authorized for use with direct channel access and DC of up to 100 %.

7.3 Information on relevant standard(s)

Both the CCam transmitter and DR receiver will comply with requirements established by an expected specialized ETSI harmonised standard which may be derived from applicable sections of ETSI EN 300 220-1 [i.7] covers Short Range Devices operating between 25 MHz and 1 GHz.

8 Radio spectrum request and justification

The UHF range below 700 MHz is in general the most optimal and indeed the only reasonable choice of operational frequency band for the proposed CCam application. This is due to the fact that in this frequency range the human body's attenuation is relatively low, typically between 20 dB to 60 dB - highly variable from patient to patient and greatly dependant on the location and orientation of both CCam and DR antenna.

In higher frequencies where greater bandwidth is more readily available, the body attenuation gets higher. For example, in the 2,4 GHz ISM band and the transmitter DC power requirements are greater which will lead to more rapid premature battery depletion.

Of the bands available to SRDs below 700 MHz, the band 433,05 MHz to 434,79 MHz was considered the best candidate of operational frequency band for CCam uplink. However its available bandwidth of approx. 1 700 kHz is far insufficient to accommodate the bandwidth necessary for transmitting signal of sufficient quality.

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. However the natural demand for highest possible resolution of medical diagnostic images led to the current situation on the market with GI endoscopes already offering megapixel resolution, thus it may be expected that also CCams would develop to match that resolution eventually.

As regards the imaging rate, tests showed that when the CCam moves rapidly through the GI tract (during a peristaltic wave), up to 20 images per second are required from each 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 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, and it is also possible to vary the initial imaging bit stream by reducing the frame rate when the CCam is moving slowly.

As a result, it was established by tests and practical implementation 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. When using digital modulation (e.g. MSK) that is within the current possibilities of CCam implementation, this results in up to 10 MHz of required operational (channel) bandwidth. Any future evolution of CCam technologies in terms of increasing number of imaging sensors, their resolution and/or frame rate and the resulting demand for higher operational bandwidth would have to be compensated by evolving compression or modulation techniques.

Following on the above considerations, it is proposed to consider placing CCam uplink channel around the globally harmonised ISM band 433,05 MHz to 434,79 MHz, but with allowed channel bandwidth of up to 10 MHz. Accordingly, the operating CCam uplink band would extend to 430 MHz to 440 MHz.

9 Regulations

9.1 Current regulations

The relevant primary reference regulatory document defining conditions for use of AMI and other SRD devices in Europe is the CEPT Recommendation ERC/Recommendation 70-03 [i.1].

However the current provisions of ERC/Recommendation 70-03 [i.1] would be insufficient to deploy the proposed new application of Wireless Medical Capsule Endoscopy, because:

- Annex 1 on "Non-specific Short Range Devices" has allowance to use the band "g2" 433,05 MHz to 434,79 MHz for SRDs without DC and channel bandwidth limits, subject to compliance with transmit power density of -13 dBm/10 kHz. While the CCam transmissions would be compliant with the established power limit, however the required bandwidth of CCam signal extends beyond the entire established Operational Frequency Band of 433,05 MHz to 434,79 MHz.

- Meanwhile the annex 2 on "Tracking, Tracing and Data Acquisition" simply does not contain any band designation within 300 MHz to 1 000 MHz range, which would be necessary to accommodate the proposed new application's wideband UHF channel as constrained by the combination of very small form-factor of diagnostic devices, their limited battery capacity vs. body attenuation and minimum necessary bitrate/modulation considerations as explained in clause 8.

9.2 Proposed regulation and justification

It is therefore proposed to add a new designation of Operational Frequency Band in annex 2 "Tracking, Tracing and Data Acquisition" of the CEPT Recommendation ERC/Recommendation 70-03 [i.1] as follows:

Table 6

Frequency Band		Power	Spectrum access and mitigation requirements	Modulation/max occupied bandwidth	Notes
b1	430 MHz to 440 MHz	-40 dBm e.r.p. (see note)	Max 16 hours operation per single diagnostic disposable device	10 MHz	Limited to ultra-low power miniature medical capsule imaging camera transmitters for gastrointestinal diagnostic
NOTE: Outside test patient's phantom body.					

The proposed newly designated operational frequency band would be fully sufficient to accommodate the proposed new medical application. On the other hand, it is highly improbable that the proposed use would cause any risk of interferences to other established users of the subject frequency range, or in fact even unlikely that the proposed new application would be at all detectable beyond a few meters from patient's body, because of 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 less than generally established spurious emissions limit of -36 dBm/100 kHz;
- the very low deployment density of devices and strictly limited duration of device operation for this very niche medical application (see clause 6 - table 1);
- 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.

These general observations are substantiated by the Minimum Coupling Loss calculations provided in annex C, which prove that for a non-specific SRD receiver the maximum theoretical distance at which victim receiver, operating near sensitivity threshold, could even sense the CCam emissions would not exceed 3 meters.

Annex A:
Key Diagnostic Types of CCam and Medical Market Data

There are currently being developed different types of CCam devices, each type designed to provide optimized visualization of a specific anatomic segment of human GI tract. In general, CCam offers opportunity of performing an alternative or, e.g. for the case of "Small Bowel", the only available examination that does not have the bleeding or sedation risks associated with colonoscopy, and therefore its use would be highly beneficial and attractive to patients and doctors.

"Small Bowel" type CCam is intended for direct visualization of the entire small bowel for detection of lesions associated with Crohn's disease, Iron Deficiency Anaemia (IDA) and obscure gastrointestinal bleeding (OGIB). Currently no other type of medical technology is available to perform this kind of examination.

The term Inflammatory Bowel Diseases (IBD) applies to a subset of chronic intestinal diseases, known as Crohn's Disease (CD) and Ulcerative Colitis (UC). IBD has a global prevalence of 2,1 million people, comprised of 1 million people with Crohn's disease.

Crohn's Disease and Ulcerative Colitis are inflammatory bowel diseases that cause chronic inflammation and damage to the Gastrointestinal (GI) tract. The GI tract is responsible for the digestion of food, absorption of nutrients, and elimination of waste. Inflammation impairs the ability of the affected GI organs to function properly, leading to symptoms such as persistent diarrhoea, abdominal pain, rectal bleeding, weight loss, and fatigue.

Crohn's disease is a lifelong and chronic relapsing inflammatory bowel disease (IBD) potentially affecting any portion of the gastrointestinal tract from the mouth to the anus. Half of all CD cases involve the ileum and colon, and in 20 % of cases, only the colon is affected. The small bowel is the most commonly affected site. It is the only site involved in ~30 % of cases and therefore can be difficult to diagnose.

Ulcerative colitis is limited to the large intestine (colon) and the rectum. It usually begins in the rectum and lower colon, but may also spread continuously to involve the entire colon.

With CD confined to the small bowel 1/3 of the time, comprehensive evaluation of the small bowel is important to make a definitive CD diagnosis, determine extent and severity of disease, and determine the baseline to serve as a comparator for monitoring the disease. Once diagnosed, patients will have ongoing monitoring to effectively treat inflammation and symptoms.

Worldwide prevalence of Crohn's disease has been increasing over the past decade. Crohn's disease has a prevalence of approximately 600 000 people in the US and 400 000 in Europe. Incidence rates are higher in western countries such as the US, Canada and Germany, but lower in Asian countries.

Procedures for diagnosis and monitoring include Small Bowel Radiography, CT Enterography/Enteroclysis, and Colonoscopy with ileioscopy, Push Enteroscopy, and Magneto-resonance Enterography.

On average, actively monitored Crohn's patients receive 2,2 treatment procedures annually, 50 % of which are radiological. Because of the increased cancer risk by ionizing radiation later in life, conventional radiology (small bowel follow-through) or computed tomography (CT), CCam is preferable method for monitoring.

"Colon" type CCam is an alternative to endoscopic visualization for diagnosis of colonic disorders. Globally, colorectal cancer (CRC) is the fourth most common cause of cancer death. There are about 1,4 million newly diagnosed cases and 694 000 deaths annually. CRC incidence varies widely across the globe with the majority of cases (55 %) occurring in more developed countries. CRC incidence and mortality increase significantly with age, with 90 % of new cases diagnosed in adults 50 years and older.

Although CRC is relatively easy to treat when detected early, screening compliance in the population still remains relatively low. Only an estimated 65 % of US citizens aged 50 and above are compliant with screening guidelines, leaving 23 million people still at risk. Compliance in other countries around the world is significantly lower, which compliance rates in Germany, for example, being less than 5 %. Even in countries with organized screening programs using stool tests first line, such as Denmark, capacity for colonoscopy cannot keep up with the demand for patients who have had a positive stool test. CCam can help further triage patients in these markets to help reduce the burden of regular colonoscopy, ensuring only the patients with actual colonic findings needing treatment get referred and undergo a therapeutic colonoscopy.

Screening can prevent CRC because tests that can directly visualize the colon mucosa, such as colonoscopy and CCam, can detect early, pre-cancerous polyps unlike stool-based tests that primarily are designed to detect cancer after it has already developed within the colon. Although most polyps will not become cancerous, removing them can prevent cancer from occurring. 40 % of CRC patients are diagnosed with localized-stage disease (confined to just the colon), and these patients have a 5 year survival rate of over 90 %.

Most of the world does not have a formal CRC screening program, and where programs exist, the primary modality is an inexpensive stool test (e.g. 94 % of all screening in Europe are performed with stool test). Only a handful of countries offer colonoscopy as a primary screening modality, including the US, Germany, Poland and Austria. Traditional optical colonoscopy is not used as a screening test in other countries either because of the substantial costs associated with its use for this indication are unacceptable or because the human resources and facilities required to provide the service are unavailable.

Annex B:
ITU Radio Regulations and ECA footnotes pertaining to band 430 MHz to 440 MHz

The ECA footnotes and ITU Radio Regulations footnotes as pertaining to subject band and CEPT countries [i.2].

- EU12: "*The applicable RR 5 footnotes in column 1 remain in force. Administrations are however urged to aim for the fullest possible harmonisation with the ITU Table of Allocations and ECA*."

- 5.138: "*The following bands: …, 433.05-434.79 MHz (centre frequency 433,92 MHz) in Region 1 except in the countries mentioned in No. 5.280, … are designated for industrial, scientific and medical (ISM) applications. The use of these frequency bands for ISM applications shall be subject to special authorisation by the administration concerned, in agreement with other administrations whose radiocommunication services might be affected. In applying this provision, administrations shall have due regard to the latest relevant Recommendation ITU-Rs.*" [i.8].

- 5.271: "*Additional allocation: in Belarus …, the band 420-460 MHz is also allocated to the aeronautical radionavigation service (radio altimeters) on a secondary basis.*" [i.8].

- 5.274: "*Alternative allocation: in Denmark, Norway, Sweden and Chad, the bands 430-432 MHz and 438-440 MHz are allocated to the fixed and mobile, except aeronautical mobile, services on a primary basis.*" [i.9].

- 5.275: "*Additional allocation: in Croatia, Estonia, Finland, Libya, The Former Yugoslav Republic of Macedonia, Montenegro and Serbia, the bands 430-432 MHz and 438-440 MHz are also allocated to the fixed and mobile, except aeronautical mobile, services on a primary basis." [*i.10*]*.

- 5.276: "*Additional allocation: in …, Greece, …, Italy, …, Switzerland, …, Turkey and Yemen, the frequency band 430-440 MHz is also allocated to the fixed service on a primary basis and the frequency bands 430-435 MHz and 438-440 MHz are also allocated to the mobile, except aeronautical mobile, service on a primary basis.*" [i.10].

- 5.277: "*Additional allocation: in …, Armenia, Azerbaijan, Belarus, …, the Russian Federation, Georgia, Hungary, …, Poland, …, Slovakia, Romania, … and Ukraine, the band 430-440 MHz is also allocated to the fixed service on a primary basis.*" [i.9].

- 5.279A "*The use of the frequency band 432-438 MHz by sensors in the Earth exploration-satellite service (active) shall be in accordance with Recommendation ITU-R RS.1260-1. ... The provisions of this footnote in no way diminish the obligation of the Earth exploration-satellite service (active) to operate as a secondary service in accordance with Nos. 5.29 and 5.30*." [i.10].

- 5.280: "*In Germany, Austria, Bosnia and Herzegovina, Croatia, The Former Yugoslav Republic of Macedonia, Liechtenstein, Montenegro, Portugal, Serbia, Slovenia and Switzerland, the band 433.05-434.79 MHz (centre frequency 433.92 MHz) is designated for industrial, scientific and medical (ISM) applications. Radiocommunication services of these countries operating within this band must accept harmful interference which may be caused by these applications. ISM equipment operating in this band is subject to the provisions of No. 15.13*." [i.8].

- 5.282: "*In the bands 435 - 438 MHz, …, the amateur-satellite service may operate subject to not causing harmful interference to other services operating in accordance with the Table (see No. 5.43). Administrations authorising such use shall ensure that any harmful interference caused by emissions from a station in the amateur-satellite service is immediately eliminated in accordance with the provisions of No. 25.11*." [i.8].

- 5.283: "*Additional allocation: in Austria, the band 438 - 440 MHz is also allocated to the fixed and mobile, except aeronautical mobile, services on a primary basis*." [i.8].

Annex C:
Estimating maximum sensing range of CCam emissions by other spectrum users

This annex provide calculation of maximum sensing ranges of CCam emissions by a considered victim application: non-specific SRD. The respective calculations provided in table C.1.

Table C.1: MCL calculation of sensing range of CCam emissions by Non-specific SRD

Parameter	#	Value	Remarks
Frequency, GHz	A	0,43	
Interfering TX power, dBm	B	-40	
Interfering TX bandwidth, kHz	C	10 000	
Interfering TX antenna gain, dBi	D	2,15	
Victim RX bandwidth, kHz	E	25	
Victim RX antenna gain, dBi	F	-2,85	
Victim RX sensitivity, dBm	G	-112	
Victim RX wanted signal margin, dB	H	10	
Victim RX C/I objective, dB	I	8	
Victim RX interference threshold, dBm	J	**-110**	J = G + H - I
Bandwidth correction factor, dB	K	**-26**	$K = -10 \times LOG_{10}(C/E)$
Minimum Coupling Loss value, dB	L	**43,3**	L = B + D + K + F - J
Maximum sensing range, m (non line of sight)	M	**3**	$M = 10^{(L - 32,5 - 20 \times LOG10(A)) / 35}$ (see note)
Maximum sensing range, m (line of sight)	M	**8**	$M = 10^{(L - 32,5 - 20 \times LOG10(A)) / 20}$
NOTE: Sensing range calculation based on path loss model with propagation exponent of 3,5, which corresponds to propagation in urban environments.			

The methodology used in the above calculations is a standard Minimum Coupling Loss technique, which provides maximum theoretical range at which the victim can sense the emissions from interfering transmitter. In reality the risk of actual interferences will be a low probabilistic number proportional to the very low chance of all events (active transmissions the CCam being within 3 m of each other) occurring simultaneously.

History

Document history		
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