Electronic Communications Committee (ECC)
within the European Conference of Postal and Telecommunications Administrations (CEPT)

COEXISTENCE BETWEEN ULTRA LOW POWER ACTIVE MEDICAL IMPLANTS DEVICES (ULP-AMI) AND EXISTING RADIOCOMMUNICATION SYSTEMS AND SERVICES IN THE FREQUENCY BANDS 401–402 MHz AND 405–406 MHz

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EXECUTIVE SUMMARY

The 401-402 MHz and the 405-406 MHz frequency bands were selected for the emerging medical implant technologies, using Ultra Low Power – Active Medical Implants (ULP-AMI) and ULP-AMI-P (peripheral devices for ULP-AMI*)* applications, based on analysis of several factors:

- these frequency bands have a relatively low ambient noise due to its primary usage by the Meteorological Aids (MetAids);
- miniature manufacturing components are readily available;
- the band lends itself to small antenna designs and most importantly;
- electromagnetic fields can propagate acceptably through human tissue in this frequency band.

The requested additional spectrum allocation will permit data download for mass storage as well as continuous transmission for those ULP-AMI/ULP-AMI-P applications requiring such operation while maintaining the integrity of the current 402-405 MHz allocation to ULP-AMI/ULP-AMI-P, typified by Medical Implant Communications Systems (MICS).

This report provides sharing study analysis between the ULP-AMI and the existing applications in the 401-402 MHz and 405-406 MHz bands.

It is concluded that no interference will be caused to other users of the bands by ULP-AMI/ULP-AMI-P, as described in sections 3 and 4 of this report.

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Coexistence between Ultra Low Power Active Medical Implants devices (ULP-AMI) and existing radiocommunication systems and services in the frequency bands 401–402 MHz and 405–406 MHz

1 INTRODUCTION

This document provides relevant sharing study analysis related to co-channel operation with Meteorological Aids Service (MetAids) in the 401 – 402 MHz and 405 – 406 MHz bands. The MetAids Service must not be disturbed or interfered with by ULP-AMI/ULP-AMI-P operating in the bands as proposed in TR 102 343 V1.1.1 [1].

This ECC Report assesses interference issues that could occur between ULP-AMI/ULP-AMI-P Short Range Devices (SRDs) and existing systems in the above bands. The medical implant systems that are proposed for deployment in the above bands are based on use of an interference avoidance technique or an interference mitigation technique that is selected based on the power output of the system transmitter.

Briefly, the interference avoidance techniques are:

- (Type 1) Listen Before Talk (LBT): to select a frequency band with a low ambient signal coupled with Adaptive Frequency Agility (AFA) to use the selected band, and
- (Type 2) very low Duty Cycle (DC) (≤ 0.1%) with a reduced transmit power level.

The ITU-R allocated the frequency bands 401 – 402 MHz and 405 – 406 MHz to the MetAids on a primary basis in all three ITU regions. Thus these bands are ideal for medical implant technology since they support worldwide recognition and use of the band for medical implant communications and have a relative low ambient signal level. World-wide recognition of the band for medical implant communications is needed for implant technology in order to support free movement of implanted patients.

The proposed interference avoidance techniques will reduce the possibility of interference to MetAids while providing for increased reliability of the medical communications transmission link in the case of use of LBT and AFA whereas the extremely low DC and low power technique will reduce the possibility of the medical radio link to interfere with the MetAids transmissions. The aim of this study is to determine the interfering distances between ULP-AMI SRDs and MetAids and to assess the sharing possibilities between both types of interference avoidance techniques in ULP-AMI: Type 1 and Type 2 on the one hand and the MetAids equipment on the other hand. A discussion of the interference affects relative to the medical systems from MetAids transmitters is also presented.

1.1 ULP-AMI systems operating in the band 401-402 MHz and 405-406 MHz

The 401-402 MHz and the 405-406 MHz frequency bands have been identified for emerging medical implant technologies based on an analysis of many factors including the proximity to the existing 402-405 MHz band for ULP-AMI (RF circuits for implants) and ULP-AMI-P (peripheral devices for ULP-AMI*)* equipments.

These frequency bands have a relatively low ambient noise due to its primary usage by the MetAids service and they are sufficiently wide to be capable of reliably supporting high data rate transmissions. In addition, miniature manufacturing components are readily available due to development of components for the 402-405 MHz band. Further, the bands lend themselves to small antenna designs and most importantly, electromagnetic fields can propagate acceptably through human tissue in these frequency bands. These factors are critical in developing technology that can be implanted in patients and still have a life expectancy of 5 to 10 years before requiring replacement.

With this additional spectrum, other types of communication services and devices could be provided to the medical community that would not otherwise be available such as body worn sensors, continuous transmission capability, external peripheral to external peripheral communications and relay of data to mass storage equipment.

2 TABLE OF FREQUENCY ALLOCATIONS

Within the ERC Report 25 [2], which contains the European Table of Frequency Allocation, the band 401-406 MHz is allocated to MetAids on a primary basis.

The band 402-405 MHz has already been allocated by CEPT for ULP-AMI on the basis of Recommendation ITU–R SA.1346 [3] and CEPT DEC (01)17 [4] (see CEPT/ERC/Rec 70-03 [5], annex 12, band a).

3 DESCRIPTION OF ULP- AMI SYSTEMS IN THE BAND 401-402 MHz AND 405-406 MHz

Active Implantable Medical Device (AIMD) systems proposed for the above bands consist of devices implanted within the body (ULP-AMI), body worn sensors (ULP-AMI), or peripherals external to the body (ULP-AMI-P) that must be able to communicate with each other in order to allow the transfer of data between the system devices. The communications content can be either: stored data, telecommand or telemetry. Other than the unique technological requirements that are essential to radio systems, integrated in an AIMD (size limits, power consumption and impedance considerations), they can be considered as typical data telemetry and telecommand devices using conventional modulation formats with proprietary telemetry protocols.

ULP-AMI devices are placed in the body to deliver therapies and/or provide diagnostic data that is used by a physician to determine the condition of the implant-wearing patient and develop appropriate therapies. External devices (ULP-AMI-P) operating under the provisions of the present document support the operation of the implanted devices (ULP-AMI) by providing a means for programming or altering the programming of the implanted device, retrieving medically related diagnostic data from the implant, transferring data to a mass storage system and to provide real time read-out of the monitored physiological parameters.

ULP-AMI must consume very little power and be extremely small in size. The implant or body worn sensor itself must contain a medical therapeutic section as well as an interface circuit to a radio system and the radio system itself. Based on the sharing analysis and the usage conditions envisioned for these devices (Recommendation ITU-R SA.1346 [3]), a power level of a maximum of 25 µW e.r.p. was determined as adequate for medical systems. This power level permits a highly reliable communications link at a distance of 2-3 m.

Two different kinds of ULP-AMI/ULP-AMI-P were considered for this study as shown in Table 1: those using LBT with AFA (Type 1) and those having very low power and a very low duty cycle (Type 2).

Parameter	**Type 1 (ULP-AMI and ULP-AMI-P)**		**Type 2 (ULP-AMI and ULP-AMI-P)**
	Uplink	**Downlink**	**Uplink (Transmit only system, Downlink N/A)**
Bitrate	50 kbit/s	25 kbit/s	50 kbit/s
Channel Bandwidth	100 kHz	50 kHz	100 kHz
Duty Cycle	50%	50%	≤0.1%
Power	-16 dBm (-46 dBW e.r.p.)	-16 dBm (-46 dBW e.r.p.)	-36 dBm (-66 dBW e.r.p.)

Table 1: ULP-AMI/ULP-AMI-P Technical Specifications

3.1 Spectrum requirements

With the development of new medical sensor technologies there is now a need for spectrum that provides for higher rates of data collection and transfer, with periodic transmissions of the order of 1 per minute or greater. Such systems will potentially collect large amounts of data that must be downloaded to mass storage media if it is to be permanently saved. The requested additional spectrum allocation will permit data download for mass storage, as well as continuous transmission for those applications requiring such operation, while offering the possibility to maintain the integrity of the current 402-405 MHz allocation to devices typified by Medical Implant Communications Systems (MICS) that are to be considered as life supporting devices transferring time-critical data.

Today, medical device manufacturers have developed applications for implant technology that will place much greater demands on the available spectrum due to increased proliferation of devices and a need for much greater transmission duration. Additional spectrum is required to handle the increased demand. Further, some types of operations, such as transmission from one external device to another external device, are not permitted under the existing standard (EN 301 839-1 V1.1.1 [6] and EN 301 839-2 V.1.1.1 [7] that apply to CEPT/ERC Recommendation 70-03 [5] Annex 12 band (a) devices). The proposed usage of the bands 401-402 MHz and 405-406 MHz is only for ULP-AMI/ULP-AMI-P systems, which do not transmit time-critical data.

TR 102 343 V1.1.1 [1] proposes that ULP-AMI and ULP-AMI-P can operate with 250 nW e.r.p and ≤0.1 % DC, as alternative to implementing LBT coupled to AFA as described in Recommendation ITU-R SA.1346 [3]. In this regard, it deviates from the conditions included in the Recommendation ITU-R SA. 1346 [3] and the sharing study coupled to it (interference with MetAids) by recognizing that interference to certain ULP-AMI/ULP-AMI-P can be accepted for some medical applications.

4 COMPATIBILITY ANALYSES

4.1 Meteorological Aids (MetAids)

4.1.1 Typical characteristics of Meteorological Aids

The term MetAids is used to describe a variety of types of meteorological equipment; radiosondes, dropsondes and rocketsondes. MetAids are flown worldwide for the collection of upper atmosphere meteorological data for weather forecasts and severe storm prediction, collection of ozone level data, and measurement of atmospheric parameters for various military applications. The data collected from these flights, or soundings, is of extreme importance for the protection of life and property through the prediction of severe storms and providing vital data for commercial airlines operations.

The observations are produced by radiosondes carried by ascending balloons launched from land stations or ships, or dropsondes deployed from aircraft and carried by a parachute. Radiosonde observations are carried out routinely by almost all countries, two to four times a day. The observations are then circulated immediately to all other countries within a few hours. The observing systems and data dissemination are all organized under the framework of the World Weather Watch Program of WMO (World Meteorological Organisation).

The main characteristics of radiosonde systems (further details are provided in Annex 1) are given below.

Link function	=	Analogue and digital transfer from radiosonde to land-based receiver using FSK
Modulation type	=	FM
Receiver bandwidth (Br)	=	300 kHz
Transmitter output power level	=	-6 dBW (250mW)
Transmitter antenna gain	=	2 dBi
Free space loss at 200 km	=	130.5 dB
Excess space path loss (fading, etc.)	=	3 dB
Receiver antenna height	=	10 m

Receiver antenna gain (Gr)	=	10 dBi
Antenna pointing error	=	3 dB
Received power level	=	-130.5 dBW
Allowed carrier to interference	=	10 dB
Maximum permissible interference level (I)	=	-140.5 dBW (on 300 kHz BW)
Equivalent power flux density	=	-155.8 dB (W/m²/4kHz).

4.1.2 Coexistence between the Meteorological Aids Service (MetAids) and MICS in the band 401-406 MHz

Maintaining the viability of the extensive MetAids infrastructure is of great importance to the public. Within this group of users, radiosondes appear to have the greatest susceptibility to interference. The e.r.p. of ULP-AMI-P (e.g. programmers) is limited in order to accomplish the desired communications without causing interference to MetAids.

The following analysis is based on the Minimum Coupling Loss concept. It uses free space attenuation, which is worst case for outdoor equipment, and modified free space including additional 12 dB loss (12 dB is an average between commercial and residential construction) for wall attenuation for indoor equipment.

ITU-R Recommendation SA.1346 [3] provides results of sharing between the MetAids and MICS operating in the mobile service in the frequency band 401-406 MHz. MICS devices in the 402-405 MHz band use LBT and AFA to avoid interference from or to MetAids (see Harmonized Standard EN 301 839 –2 V1.1.1 [7]), as well as interference from/to other MICS systems in the band.

It is proposed that ULP-AMI and ULP-AMI-P also can operate with ≤0.1 % duty cycle as alternative to LBT coupled to AFA, to avoid interference to MetAids.

Recommendation ITU-R SA.1262 [8] specifies that the interfering power to be received no more than 20% of the time is -161.9 dBW/300 kHz. Recommendation ITU-R SA.1346 [3] used 20 dB for building attenuation and determined that a MICS device must be within 421 m to interfere with radiosonde operation. Note the use of the conservative assumption that the ULP-AMI/ULP-AMI-P frequencies and the radiosonde frequencies are perfectly aligned.

Clearly, the ultra low transmit power of the ULP-AMI/ULP-AMI-P equipment greatly reduces the interference potential. However, the probability of interference is also reduced by other factors that, while difficult to quantify, remain important.

The method used to calculate the distance at which there is a worst case potential for interference to the radiosonde receiving station from the implant or its associated external equipment is based on the required propagation path loss to prevent a medical implant transmitter from interfering with the radiosondes receiving station. Worst case would obviously apply for co-channel operation for the case of a non-LBT and AFA MICS system at 25 µW e.r.p.

4.1.2.1 Path Loss

The required path loss can be calculated using the following equation to determine the minimum required attenuation to prevent interference to the radiosonde receiving station:

$$Pl = C/I - C + Pt + Gr + Gt$$

where: Pl: Propagation loss

C: Nominal received signal power from desired radiosonde signal

C/I: Carrier to Interference ratio

Pt: Implant system maximum transmit power of 25 µWatts.

Gr: Radiosonde receiver antenna gain

Gt: Implant system transmitter antenna gain

The radiosonde receiver, having the larger bandwidth, will always have its frequency band included in the band of the implant system transmitter that has a much lower bandwidth for co-channel operation.

Substituting parameters from typical ULP-AMI technical specifications listed in Table 1 in section 3 into the above equation:

ULP-AMI Type 1: Pl = 10 - (-130.5) + (-46) +10 +2.15 = 106.6dB

ULP-AMI Type 2: Pl = 10 - (-130.5) + (-66) +10 +2.15 = 86.6 dB

This is the necessary path loss attenuation that must be ensured to preclude interference from occurring to a radiosonde receiver station from medical implant system transmitters operating at a power levels of – 46 dBW and -66 dBW.

4.1.2.2 Separation Distance

To calculate separation distances to preclude interference, consider two propagation models – one corresponding to free space and another corresponding to modified free space. These models would correspond to the following usage scenarios:

1) patient outdoors with external implant transceiver located nearby or carried by the patient with the radiosonde receiving station nearby, *i.e*., free space transmission path, and

2) patient indoors (12 dB wall attenuation is an average based on construction types ranging from commercial buildings to single family residences) with external implant transceiver located nearby or carried by the patient with the radiosonde receiving station nearby, i.e., modified free space to account for building attenuation.

Line-of-sight is appropriate to apply since the radiosonde receiving stations are relatively low to the ground and have omni-directional antenna in order to track the signal from the radiosonde down-range as far as possible.

From the path loss requirement we can compute the separation distance requirement and from this determine the geographic area on the earth where interference will occur as a function of radiosonde height for the above two models.

4.1.2.3 Free Space, Patient outdoor

Path loss (Pl) = 32.4 + 20 log(f) + 20 log(d) = 32.4 + 20 log(401.5) + 20 log(d)

Substituting: 106.6 = 32.4 + 52.1 + 20 log(d)

Then d = 12.7 km for Type 1 ULP-AMI with free space attenuation

Path loss (Pl) = 32.4 + 20 log(f) + 20 log(d) = 32.4 + 20 log(401.5) + 20 log(d)

Substituting: 86.6 = 32.4 + 52.1 + 20 log(d)

Then d = 1.27 km for Type 2 ULP-AMI with free space attenuation

4.1.2.4 Modified Free Space to include building attenuation, Patient indoor

Actual wall attenuation factors are closely associated with building construction, with nominal values ranging from about 5 dB to 18 dB or higher. For purposes of this analysis, a factor of 12 dB wall attenuation is used as a median between various building constructions (commercial and residential) due to location of the patient implant system transmitter indoors.

Path loss (Pl) = 106.6 - 12 = 32.4 +52.1 +20 log(d)

Calculating: d = 3.2 km for Type 1 ULP-AMI with modified free space attenuation

Path loss (Pl) = 86.6 - 12 = 32.4 +52.1 +20 log(d)

Calculating: d = 0.32 km for Type 2 ULP-AMI with modified free space attenuation

Above calculations are summarised in Table 2.

Implant Transmitter Type / Power Output	Free Space, distance between Radiosonde receiver and Implant Tx outdoor (km)	Modified Free space, distance between Radiosonde receiver and Implant Tx, indoor (km)
Type 1 / -46 dBW	12.7	3.2
Type 2 / -66 dBW	1.27	0.32

Table 2: Required Separation Distances

4.1.3 Summary on the compatibility analyses for MetAids

The section concerning MetAids indicates that the higher power Type 1 systems have a potential to interfere with the receiving stations of radiosonde transmitters. However, it is proposed that these higher power systems must incorporate LBT techniques to select available spectrum and AFA to provide the ability to move to the selected frequency for operation. Systems using LBT (Type 1), based on the applicable standard developed for implantable systems in an adjacent band, will have a threshold sensitivity, $P_{TH,}$ lower than given by the equation:

$$10 \log B(Hz) - 150 + G \, (dB_i)$$

where G is the gain of the frequency monitoring system antenna.

Further, if during medical implant's communications session a radiosonde transmitter drifts into the band occupied by the medical system, it will interfere with the medical system communications causing the medical system to re-scan the band and select a new frequency on which to continue its communications.

For the fixed frequency 250 nW (Type 2) systems, the required separation distance is of the order of 1.27 km for the outdoor model and 0.32 km for the indoor model. Here one must rely on probabilities for interference reduction. Considering a duty cycle limit of 0.1% and the drift in frequency of radiosondes, the probability of interference to radiosondes receiving equipment is estimated to be of the order of less than 1% for situations where radiosonde receivers are actively receiving incoming signals from radiosondes continuously in extreme weather conditions.

It is vital that patients suffer no harmful effects from interference from any source including other medical systems. Obviously systems employing LBT coupled with AFA, error detection and correction schemes and data re-transmission of any corrupted packets provide a greatly enhanced level of protection to the patients from interference. However, even these techniques may not be sufficient to eliminate all interference with the expected proliferation of medical implant sensors and devices as described in the literature.

Type 2 fixed frequency transmit-only systems, however, can not rely on any technique other than error detection to provide protection from interference. They can not move to clear spectrum and they can not be given instructions to re-transmit data that is corrupted. It is clear that a very real threat of interference to the medical systems exists from many sources and medical implants are not offered any protection from interference due to their classification as an SRD.

Based on the above, it is proposed that consideration be given to clearly stipulating in the legislation that devices operating in the proposed bands may suffer interference.

4.2 Impact study of ULP-AMI on Earth Exploration Satellite Service (EESS) in the band 401-402 MHz

4.2.1 EESS Protection Requirements

The band 401-402 MHz is used for EESS (Earth to Space) with Primary allocation status, especially for Data Collection and Location purposes. The corresponding systems provide a worldwide in-situ environmental data collection and Doppler-derived location service. Those systems have been designed and optimised as based on the random access concept, i.e. short unidirectional messages (< 1 s) with a high time interval (> 60 s) and a low bit rate (400 bps). This concept allows simple space platforms with a low energy consumption and hence, the possibility to develop economical and/or mini platforms.

The calculations below have been conducted for the worst case. An activity factor of 100% was assumed. In reality, it is expected to be much lower.

ITU-R Recommendation SA.1163-2 [9] specifies that the interfering power to be received no more than 20% of the time is -178.8 dBW/1600 Hz for non-GSO data collection, with low gain antenna. It means a threshold *S*=-180.8 dBm/Hz.

4.2.1.1 Single entry interference case

The link budget between an ULP-AMI (outdoor) and a satellite receiver is given by the following equation in dB:

$$P_R = erp + L_{FS} + G_R + 2.15$$

where:

- P_R : Received power in dBm/Hz at the satellite, coming from ULP AMI device;
- *erp:* e.r.p. of the ULP-AMI device in dBm/Hz. Following assumptions given in section 4.2, two types of devices could exist. The worst e.r.p. is that of Type 1 system (-46dBW in 50 kHz bandwidth). Conversion between e.i.r.p and e.r.p is given by e.i.r.p.=*e.r.p.*+2.15 dB
- L_{FS} : Free space loss in dB equal to $L_{FS} = 20Log\left(\frac{\lambda}{4\pi d}\right)$ where d is the range between the ULP-AMI device and the satellite and λ is the wavelength
- G_R: Satellite antenna gain in dBi.

The Table 3 below gives the assumed values and results of calculations:

Parameter	**Symbol**	**Value**	**Unit**
Power	e.r.p.	-63	dBm/Hz
Frequency	F	401	MHz
Wavelength	λ	0.75	m
Range between the ULP AMI device and the satellite	D	830	km
Free space loss	L_{FS}	-143	dB
Satellite antenna gain	G_R	2	dBi
Received power at the satellite	P_R	-202	dBm/Hz

Table 3: Path Loss Parameters

In case of indoor ULP-AMI use, an additional reduction factor of 12 dB (the same as in section 4.1.1) must be applied to the received power. In that case, P_R = -214 dBm/Hz.

As a result and taking into account the EESS protection criterion, the resulting margin Δ in the single outdoor interferer case is about:

$$\Delta = S - P_R \approx 21dB$$

This margin increases to 33 dB for the indoor case.

4.2.1.2 Aggregate interference case

These margins can be used to estimate the allowable density of ULP-AMI devices within the footprint of a satellite.

For that purpose, one can consider an apportionment of ULP-AMI devices between indoor (80%) and outdoor use (20%).

The two previous margins expressed in terms of amount of ULP-AMI devices ($\Delta = 10Log(N)$) become:

- Indoor: N=1995
- Outdoor: N=126

So, the maximum number of ULP-AMI (indoor and outdoor) devices within the footprint of a satellite is about 2121.

If one considers the following assumptions:

- Half geocentric angle: 23.18°
- Radius of the satellite footprint for a minimum ground station elevation angle of 5° assuming a flat earth: 2580 km

The coverage area of a typical satellite is around 21 millions of km².

The resulting density provides for quite few ULP-AMI devices, but this could be improved by considering the very low probability that ULP-AMI and EESS emissions are received at the same time. Indeed, both transmissions are made with short bursts. A more appropriate activity factor could also be considered.

For example, it is proposed to consider a ≤0.1% duty cycle as alternative to LBT. If this activity factor is considered, the number of ULP-AMI grows from 2121 to 2.1 millions of devices.

Despite this worst case analysis, it would appear that the band 401-402 MHz could accommodate a large number of ULP-AMI devices without causing harmful interference to the EESS existing service. Operation at an e.r.p. of -16 dBm or less in the EESS band 401-402 MHz can support MICS with a low probability of interference to the EESS.

4.3 Impact of ULP-AMI /ULP-AM-P on Meteorological-Satellite Systems (MetSat) [E/s] in the band 401-402 MHz

It is recognized that there is a strong similarity between EESS and MetSat systems. Therefore the sharing analysis related to compatibility between EESS and ULP-AMI/ULP-AMI-P devices in the 401-402 MHz band should be applicable to Meteorological Satellite (MetSat) applications. It was confirmed that the band 401-402 MHz for MetSat is only used for up-links (Earth to space). In this case there is no concern to be expressed about interference by ULP-AMI/ULP-AMI-P operating in the band.

4.4 Impact of ULP-AMI/ULP-AMI-P on Emergency Position Indicator Radio Beacon (EPIRB) in the band 406–406.1 MHz

Maintaining the viability of the EPIRB service is of paramount importance. EPIRBs are used to provide location information to rescue personnel in general emergency situations. The EPIRB transmitters radiate signals at a power level of 5 watts. The signal is received via a series of satellites and the location information relayed to terrestrial based stations manned by rescue personnel.

Out-of-band and/or spurious emissions from ULP-AMI/ULP-AMI-P operating in the 405-406 MHz band are limited to no more than -66 dBW/100 kHz that is applicable to most land mobile equipment operating in the 30 to 1000 MHz band. Therefore no concern need be expressed about interference by ULP-AMI/ULP-AMI-P operating in the band 405-406 MHz to the EPIRB service.

5 CONCLUSIONS

Based on the conclusion of the MetAids, EESS, MetSat and the EPIRB sharing analysis, the proposed limits should allow the coexistence between the MetAids, EESS, MetSat, and EPIRB services and Type 2 ULP-AMI/ULP-AMI-P low DC low power devices in the bands 401-402 MHz and 405-406 MHz, assuming that the Type 2 ULP-AMI/ULP-AMI-P must be prepared to accept interference from the MetAids, EESS, MetSat systems.

Type 1 ULP-AMI/ULP-AMI-P, using higher output power in association with LBT and AFA will avoid receiving or causing interference to/from the above listed primary users and is not expected to be a source of interference to the primary users.

Based on implementing the technical specifications listed in this report, it is concluded that the frequency bands 401-402MHz and 405-406 MHz can be made available for the applications of Type 1 ULP-AMI/ULP-AMI-P operating with LBT/AFA at +25 µW output power, as well as applications of Type 2 ULP-AMI/ULP-AMI-P non-LBT/AFA systems operating with DC≤0.1% and maximum output power of +250 nW.

ANNEX 1: DESCRIPTION OF METAIDS SYSTEMS

Radiosondes are mainly used for *in situ* upper air measurements of meteorological variables (pressure, temperature, relative humidity, wind speed and direction) in the atmosphere up to an altitude of 35 km. The radiosonde measurements are vital to national weather forecasting capability (and hence severe weather warning services for the public involving protection of life and property).

The radiosondes and associated tracking systems provide simultaneous measurements of the vertical structure of temperature, relative humidity and wind speed and direction over the full height range required. The variation of these meteorological variables in the vertical contains the majority of the critical information for weather forecasting.

The radiosonde systems are the only meteorological observing systems able to regularly provide the vertical resolution that meteorologists need for all four variables. Identification of the heights where sudden changes in a variable occur is vital. Thus, it is essential that continuity of reliable measurements is sustained throughout the deployment cycle of the radiosonde. Apart from accuracy, the chief features required in radiosonde design are reliability, robustness, small weight, small bulk and small power consumption.

Since a radiosonde is generally used only once, it is typically designed for production at low cost. Ease and stability of calibration are also important factors. A radiosonde should be capable of providing data over a range of at least 200 km and operating in a temperature range from – 90 °C to 60 °C. Since the voltage of a battery varies with both time and temperature, the radiosonde must be designed to accept the variations without exceeding the accuracy and radio-frequency drift requirements. The associated ground equipment should not be unduly complicated or require frequent highly skilled maintenance. It is preferable, however, to keep the radiosonde itself as simple as possible, even at the expense of complication in the ground equipment, since failure of the latter is more readily corrected and since the costs of flight equipment should be kept to a minimum.

The ascent time of a full radiosounding is about 90 min, and the descent time is about half of the ascent time if a parachute is used. The radiosonde is usually still transmitting while descending. The maximum range for the proper reception of the radiosonde signal is about 200 to 350 km. The ascent speed is about 5 m/s and the trajectory depends on the prevailing wind conditions. In general, within an area of radius about 400 to 650 km around the radiosounding station the same downlink frequency cannot be used. In high density areas, more than ten radiosonde operators are located within the effective area of one radiosonde.

A radiosonde system consists of a balloon borne ascending radiosonde or a parachute descending dropsonde, and a receiving land-based station which receives signals transmitted from the radiosonde. A radiosonde sends typically one full data frame in one second. The modulation is analogue FM modulation of the carrier frequency. A data frame consists of direct readings of meteorological sensors (pressure, temperature, relative humidity, wind speed and direction) and a set of reference data which are used to resolve the meteorological sensor readings.

Radiosondes are mainly used for upper air measurements from the surface up to altitudes of between 20 and 35 km. They will often drift more than 100 km from the launch site before falling to earth, and sometimes more than 300 km when upper wind are stronger. During these flights there will be many instances where radiosondes will cross over heavily populated areas. More than 150,000 radiosondes per year are launched for this purpose from 214 launch sites across Europe. Of these stations, 111 use the MetAids systems operating over the band 401 – 406 MHz or in specific portions of the band.

The measurements are mostly performed routinely at 00 and 12 UTC, but in some countries in Europe where significant changes in weather are common the separation between two measurement sequences can be reduced to 6 hours. The separation between two measurements can be further reduced down to 3 hours for specific research into severe weather over large areas in Europe and for several days in a row. The radiosonde will usually transmit for about 3 hours during one launch.

The radiosonde passes each layer of the atmosphere only once and sends data to the land-based receiver every second. If the data is lost because of harmful interference, there are no retransmission possibilities from the radiosonde. An interference occurring during a brief period of less than one second generally causes the loss of one of the measured variables. This is enough to corrupt the whole measurement sequence. Other systems in the MetAids service are data collection platforms and various satellite systems. Of the MetAids systems, the most likely interference victims from medical systems in the band are the radiosondes system.

ANNEX 2: LIST OF RELEVANT DOCUMENTS

[1] ETSI TR 102 343 V1.1.1 (2004-07): Electromagnetic compatibility and Radio spectrum Matters (ERM); Ultra Low Power Active Medical Implants (ULP-AMI) operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; System Reference Document

[2] CEPT/ERC Report 25: "The European table of frequency allocations and utilizations covering the frequency range 9 kHz to 275 GHz"

[3] ITU-R Recommendation SA.1346: "Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz"

[4] CEPT DEC (01)17: "ERC Decision of 12 March 2001on harmonised frequencies, technical characteristics and exemption from individual licensing of Short Range Devices used for Ultra Low Power Active Medical Implants operating in the frequency band 402 - 405 MHz"

[5] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)"

[6] ETSI EN 301 839-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods"

[7] ETSI EN 301 839-2 (V.1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM);Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive"

[8] Recommendation ITU-R SA.1262: "Sharing and Coordination Criteria for Meteorological Aids in the 400.15 – 406 MHz and 1668.4- 1700 MHz Bands"

[9] Recommendation ITU-R SA 1163-2: "Interference criteria for service links in data collection systems in the Earth exploration-satellite and meteorological-satellite services".

ANNEX 3: DEFINITIONS AND ABBREVIATIONS

Active Implantable Medical Device (AIMD): any active medical device (AMD) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Active Medical Device (AMD): any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

Adaptive Frequency Agility (AFA): ability to determine an unoccupied sub-band or channel of operation in order to minimize interference with other users of the same band.

Channelization: MICS operation will be channelised with the channel of operation selected based upon the lowest ambient noise level. A radiosonde operating at a given frequency will look like a wide-band noise source in the MICS band, causing the MICS equipment to select a different channel. Thus, when e.g. a MICS programmer (ULP-AMI-P) detects a radiosonde, it will respond in such a way that the radiosonde and the MICS programmer do not interfere with each other.

Downlink duty cycle: Due to tissue attenuation, only communication to the implanted device has the potential to interfere with MetAids. The communication exchange will likely be half-duplex and highly asymmetric, with transmission to the implanted device (ULP-AMI) occurring only a fraction of the time that the link is active. Typically, downlink will occur for only 10 ms out of every 250 ms of communication.

Interferer density: Due to the attenuation of waves launched from the body, the programmer is the only potential source of interference for MetAids users. Additionally, implanted device proliferation is limited by medical need, not consumer desire. This holds down the number of potential interferers to something much less than could be expected from a consumer or commercial application.

Interferer duty cycle: Implanted devices have a communications duty cycle of about 0.005% over their lifetime. The ULP-AMI-P (e.g. programmer), of which there are several orders of magnitude fewer, may have a much higher duty cycle.

Life supporting equipment: equipment whose continued normal operation is required in order to sustain life.

Listen Before Talk (LBT): combination of the listen mode followed by the talk mode

Medical Implant Communications System session (MICS): collection of transmissions that may or may not be continuous, between co-operating ULP-AMI and ULP-AMI-P.

Time-critical communication: transfer of data between an ULP-AMI and an ULP-AMI-P that must be successfully communicated within the shortest possible timeframe in order to provide maximum benefit to the healthcare of the patient.

Time-Critical Data: Data that must be reliably transferred from /to an implanted ULP-AMI device within the shortest possible time frame for the benefit of the healthcare of the patient.

Ultra Low Power Active Medical Implant (ULP-AMI): the radio part of an AIMD.

Ultra Low Power Active Medical Implant Peripheral device (ULP-AMI P): the radio part of equipment outside the human body that communicates with an ULP-AMI to establish a radio-link