Appendix C

Compatibility Analysis for the Sharing of Spectrum Between Medical Implant Communications Systems and the Meteorological Aids Service

INTERNATIONAL TELECOMMUNICATION UNION

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DRAFT NEW RECOMMENDATION ITU-R SA.[ ]

SHARING BETWEEN THE METEOROLOGICAL AIDS SERVICE AND MEDICAL IMPLANT COMMUNICATION SYSTEMS (MICS) OPERATING IN THE MOBILE SERVICE IN THE FREQUENCY BAND 401 – 406 MHZ

The ITU Radiocommunication Assembly,

considering

a) that the band 401-405 MHz is allocated to the Meteorological Aids Service on a primary basis;

b) that ITU-R Recommendation SA.1165 (7/BL/22) specifies the technical characteristics of radiosonde systems in the Meteorological Aids Service, and that ITU-R Recommendation SA.[7/BL/23] specifies the sharing and co-ordination criteria for Meteorological Aids operated in the band 401 – 406 MHz;

c) that the Medical Implant Communication Systems are comprised of an implantable device which is installed within the human body, and a programmer, which is designed for radiocommunication operation at 2 meters away from the body for the programming and occasional communications with the implant device;

d) that Medical Implant Communication Systems require a single band available wordwide, and may operate in the mobile service currently allocated on a secondary basis in the band 401 – 406 MHz;

e) that with a limit of –16 dBm on the e.i.r.p. of Medical Implant Communication Systems (MICS), no harmful interference would occur to the operation of Meteorological Aids from the MICS;

f) that interference mitigation techniques used by the Medical Implant Communication System equipment, as described in the Annex 1, provides a high level of protection to their operation from possible interference by Meteorological Aids systems.

recommends

1 that sharing is feasible in the band 401 – 406 MHz between the Meteorological Aids Systems, and Medical Implant Communication Systems which are in compliance with *recommends* 2 and 3; and with the technical characteristic of Annex 1.

2 that the e.i.r.p. of Medical Implant Communication System transmitters be limited to –16 dBm (25 microwatts) in a reference bandwidth of 300 kHz in order to provide adequate protection of Meteorological Aids Systems;

3 that interference mitigation techniques, as discussed in the Annex 1 should be used by Medical Implant Communication Systems to protect their operation.

ANNEX 1

FEASIBILITY OF CO-CHANNEL SHARING BETWEEN METEOROLOGICAL AIDS AND ULTRA-LOW POWER IMPLANTABLE MEDICAL DEVICES IN THE 401-406 MHZ BAND

1 Background

Millions of people worldwide depend upon active implanted medical devices to support and improve the quality of their lives. Active implants perform an expanding variety of therapeutic functions: regulating heart rates (via pacing and/or defibrillation), controlling pain, administering pharmaceuticals, controlling incontinence, and treating neurological tremors to name just a few. As the technology continues to evolve and the population ages, service to humanity from these devices will rapidly increase from an already large base.

Communication links to implanted medical devices serve a variety of purposes, with new opportunities to improve patients' quality of life constantly arising. Today, communication links are used for: device parameter adjustment (e.g. pacing rate), transmission of stored information (e.g. stored electrocardiograms), and the real time transmission of vital monitoring information for short periods (e.g. cardiac performance during the implant procedure). A communications system for medical implant devices includes a programmer and an implanted device. The programmer transmits data to the implanted device and receives data from the implanted device. The programmer operates outside the human body and contains an ultra low power transceiver and an antenna. The implanted device also contains an ultra low power transceiver and an antenna, but operates inside the human body. The implanted device receives data from the programmer and transmits data to the programmer. Current technology that relies on RF induction cannot support the requirements for higher data rates (e.g. 100 kbps).

Implanted medical device communications systems are inherently portable. Patients travel around the world and can be far from their primary physician when an emergency arises and the need for device communication occurs. Likewise, programmers are often moved between medical facilities and countries. This mobility requirement and the constraints on the system design require the availability of at least a single channel between 250 and 450 MHz for use worldwide. For medical implant communications systems (MICS) to be successful, the identification of a single, worldwide band 3 MHz wide for use by all manufacturers is vital. Operation in a portion of the band (401 - 406 MHz) appears to be the only viable option.

For effective MICS operations, the effective radiated power needs to be in the range of -20 dBm (10 uW) to -16 dBm (25 uW). This low ERP in combination with the link being used almost exclusively indoors and in urban areas virtually eliminates the potential for MICS operations to interfere with Metaids. Note also that because the device's primary purpose is therapeutic, the communication link is used only 0.005% of the device's lifetime further limiting its interference potential.

2 MICS Characteristics

2.1 Frequency of Operation

The focus on 401 - 406 MHz as the frequency band for MICS operation is the result of many factors. The frequency band selected must be capable of reliably supporting high data rate transmissions, lend itself to small antenna designs, fall within a relatively low noise portion of the spectrum, propagate acceptably through human tissue, and be feasible with circuits that require a minimal amount of electrical power.

2.2 Total Required Bandwidth

MICS operations require 3 MHz of available spectrum for the creation of at least 10 channels. These channels are used to avoid interferers and support the simultaneous operation of multiple devices in the same area (such as clinics with multiple rooms). International spectrum studies have shown that even with 3 MHz available only one or two channels will be useable in many environments.

2.3 MICS Link Budget Calculation

The parameters used for the analysis of MICS links are:

	Uplink (Implant ⇒ Programmer)	Downlink (Programmer ⇒ Implant)
Frequency	403.5 MHz +/- 1.5 MHz	
Modulation Type	FSK	
Receiver Noise Bandwidth	200 kHz	25 kHz
Ambient Noise @ Receiver Input	20 dB above kTB	≅ kTB (due to tissue loss)
Receiver Noise Figure	4 dB	9 dB
Receiver Noise Floor	-101 dBm	-121 dBm
Receive Antenna Gain	2 dBi	-31.5 dBi
Required SNR (BER = 1E-5)	14 dB	
Free Space Loss @ 2 meters	30.5 dB	
Fade Margin[1] (with diversity)	10 dB	
Excess Loss[2] (polarization, etc.)	15 dB	
Transmit Antenna Gain	-31.5 dBi	2 dBi
Power into Antenna	-2 dBm	-22 dBm
ERP	-33.5 dBm (@ body surface)	-20 dBm[3]

1 By using the same antenna as selected for uplink and keeping the downlink message time short relative to the 4 Hz fade rate, link reciprocity keeps the downlink fade depth to 10 dB in spite of the absence of spatial diversity in this direction.

2 Excess loss in the link is the result of patient orientation, antenna misalignment, obstructions (such as a physician) in the main line of sight path and polarization losses. These statistically independent processes can be meaningfully modelled by adding 15 dB of margin. Note that polarization loss occurs to varying degrees for all antenna configurations.

3 For this analysis, -20 dBm (10 uW) was used as the effective radiated power. Additional margin is desirable provided that it can be obtained without jeopardizing interference-free operation in the Metaids band and can be achieved within the design constraints imposed by the environment in which MICS stations will operate.

2.4 Duty Cycle

The primary purposes of the devices with MICS capabilities are diagnosis and therapy. Since use of the communications system reduces the device lifetime for these operations it is used only when necessary. As an example, today's low frequency RF inductive communication system is activated for only 0.005% of the implanted device's lifetime (about 4 hours out of 9 years). In the case of the programming device used by the physician the duty cycle will be much higher. In the case of a clinic with multiple programmers, overall use of the band could approach 50% during business hours.

3 Analysis of Metaids susceptibility to MICS Interference

3.1 Interference to Radiosondes

Maintaining the viability of the extensive Metaids infrastructure is of great importance to the public. Current users of the band include radiosondes, rocketsondes, dropsondes and data collection platforms. Of these users, radiosondes appear to have the greatest susceptibility to interference. The EIRP of MICS programmers needs to be limited in order to accomplish the desired communications without causing interference to Metaids.

ITU-R Recommendation SA.[7/BL/23] specifies that the interfering power to be received no more than 20% of the time is -161.9 dBW/300 kHz. Using the CCIR Standard Propagation Model [4] and 20 dB for building attenuation [5], it is determined that a MICS device must be within 421 meters to interfere with radiosonde operation. Note the use of the conservative assumption that the MICS frequencies and the radiosonde frequencies are perfectly aligned.

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

Channelization. MICS operation will be channelized with the channel of operation selected based upon the lowest ambient noise level. A radiosonde operating at a given frequency will look like a narrow band noise source to in the MICS band, causing the MICS equipment to select a different channel. Thus, when a MICS programmer detects a radiosonde, it will respond in such a way that the radiosonde and the MICS programmer not interfere with each other.

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

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4 Okumura *et al., 1968*

5 Kozono, S., and K. Watanabe, "Influence of Environmental Building on UHF Land Mobile Radio Propagation," *IEEE Trans. Commun. Com-25 (Oct. 1977);* Walker, E. H., "Penetration of Radio Signal into Building in the Cellular Radio Environment," *Bell Sys. Tech. J. 62: 9 Pt. I (Nov. 1983);* Ted Rappaport, "Wireless Communications" (Prentice Hall PTR), pp.131-132; [Tur87] Turkmani, A. M. D., Parson, J. D. and Lewis, D. G., "Radio Propagation into Buildings at 441, 900, and 1400 MHz," *Proceeding of the 4th International Conference on Land Mobile Radio*, December 1987; [Tur92] Turkmani, A. M. D., Toledo, A. F. "Propagation into and within buildings at 900, 1800, and 2300 MHz," *IEEE Vehicular Technology Conference*, 1992.

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 programmer, of which there are several orders of magnitude fewer, may have a much higher duty cycle.

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 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.

Thus, the typical radii for a MICS programmer to interfere with a radiosonde will be much less than 500 meters. In the rare case where a MICS programmer is within range, the probability of interference would be reduced by the need for MICS equipment to employ an interference avoidance algorithm to operate on a channel found to have a low noise level. The use of a low duty cycle and half-duplex operation by the MICS equipment, along with the duty cycle of the radiosonde system, also reduce the possibility of interference to Metaids.

3.2 Interference to the Radiosonde Ranging Adjunct

The MICS signal will not interfere with the radiosonde ranging adjunct. The 25 Watt transmission power of the ranging adjunct is 60 dB higher than the MICS transmission power. The following formula predicts the carrier to interference ratio (note that this model would predict a higher C/I if building losses and MICS antenna directivity were included) The worst case occurs at the end of flight when the balloon is at its maximum range from the transmitter (x<250 km, height>25 km). Under these conditions a C/I of 37 dB is predicted.

$$C/I = 4.34(12.89 + 2\ln((2rh) + x^2 + h^2 + r^2)^{1/2} - r) - \ln(x^2 + h^2))$$

where:

h = height (meters)

x = range (meters)

r = effective radius of Earth (meters)

4 Analysis of MICS Susceptibility to Interference

Clearly, it is vital patients suffer no harmful effects from interference. This must be true for potential interference from Metaids, other intentional radiators, and unintentional radiators. Patient harm can arise in three ways: the implant device communications circuitry depletes the device battery responding to false activation, the link is unavailable when needed, and data are corrupted by interference. MICS equipment can protect the patient and implanted devices using a variety of techniques.

4.1 False Alarm Tolerance.

To meet the longevity requirements of the device, the MICS implant device communications circuitry must be active only when communicating. It is, however, also necessary that the link be available on demand. To meet these conflicting requirements, the detection of a strong DC magnetic field (>14 Gauss) can be used to activate the implant device communications circuitry. Upon detecting the magnetic field, the system would go through a channel identification and acquisition algorithm. Should link establishment be unsuccessful, the implant communications circuitry would return to dormancy, conserving battery energy. This method is used today for most implanted devices and has an extremely low false alarm rate.

In cases such as home monitoring where availability on demand is not a requirement, the system could poll at a long interval (typically for less than a second every 30 to 120 minutes) to determine if the establishment of a link is desired. The presence of interference prolongs the signal qualification and channel acquisition process, wasting battery energy. To avoid this, the microprocessor could program an increased polling interval until the interference subsides. For troubleshooting purposes the MICS transceiver could also report the problem during the next successful transaction.

4.2 Interference Tolerance.

Interfering signals reduce channel availability. The signal threats fall into three categories: impulsive, narrowband and broadband. The following paragraphs describe interference management strategies for each.

By definition, impulsive interference is very short in duration and often of greater amplitude than MICS signal levels. MICS equipment can deal with this type of interference via the communications protocol. Either or both ARQ (automatic request repeat) or FEC (forward error correction) can be used to mitigate the effects of data errors caused by impulsive noise.

Narrowband interference sources are those with bandwidths comparable to the MICS waveform and narrower. This source of interference is usually from other communicators who are using the same band. Narrowband interferers will be avoided by MICS equipment through the use of frequency agility (changing the frequency of transmission) and channelization. This technique is required given the dynamics of worldwide spectrum usage and the presence of other intentional and unintentional radiators. Included in the category of narrowband interferers are the Metaids users of the band. The potential for a radiosonde to interfere with a MICS station is essentially zero. Given the typical radiosonde transmitted bandwidth of 300 kHz and the availability of 3 MHz of spectrum for MICS operations, at least ten radiosondes would have to be within 1 km to jam a MICS that employed up to 300 kHz of bandwidth per transmission. Likewise, Wind Profilers and Data Collection Platforms also have a low probability of interference. They tend to be geographically remote relative to MICS locations, with the DCP's low duty cycle and the Wind Profilers antenna directivity working to the advantage of MICS operations.

Broadband interferers have a bandwidth in excess of the MICS waveform - potentially much broader. Such interferers may cover the entire 3 MHz band, making it impossible to avoid such interference by the simple expedient of changing the frequency of transmission. As such, broadband interference sources pose a great challenge to MICS operations. Should a broadband interferer make the entire channel unavailable, the first defense would be to operate the system at reduced range. The signals at the surface of the body are approximately 1000 times stronger than at 2 meters, providing the opportunity to improve the SNR by 30 dB by moving closer to the patient. As a final resort, initial systems could deploy with both the low frequency RF inductively coupled technology and MICS transceivers, thereby allowing the use of the old system as a fallback.

An example of a type of broadband interferer are the secondary radars operating in this Meteorological Aids band in some countries for tracking radiosondes. The interference potential of such ground-based transmitters to MICS was theoretically analysed. Preliminary results indicate that a separation distance of 1.1 km produces unwanted signals in the MICS with a power spectral density equal to that of the MICS system noise. In practice, separation distances as low as 200m should be sufficient for safe operations. These computations assume that the directional tracking antenna of the secondary radar points in the direction of the MICS. A further assumption was that the radar emits a broadband CW signal. While it is unlikely that pulsed signal will call for significantly large separation distances, the exact influence of the real co-channel secondary radars will be determined in field tests.

4.3 Maintenance of data integrity

To ensure patient safety, it is vital that all data sent to and received from the device be accurate. To meet this requirement, MICS equipment can use multiple error detection techniques. First, serial numbers and/or addresses identify all links. Second, once established, cyclic redundancy codes (CRC) validate all transmitted data. Analysis shows that these codes lower the probability of incorrectly programming implant parameters to about two in a billion. Third, each operation has a limited valid command set. And finally, additional protection arises from geographic separation, operation times and the small coincidence of co-channel operation.

Clearly, the probability of a session being established and a Metaids user causing a programming error is essentially zero. More importantly, the Metaids user is not the major interference threat. Measured data show that it is common to have interferers of unknown origin in the band. The designers of MICS equipment understand it is their responsibility to insure that the signals of the Metaids users (and other radiators) will be unable to harm patients.

5 Summary

The continued development of implanted medical devices requires high speed (100 kbps) wireless short-range ultra low power data links. The successful deployment of this technology requires the identification of a worldwide 3 MHz band of suitable spectrum. Operation at EIRPs of -16 dBm or less in a portion of the Metaids band at 401 - 406 MHz can support Medical Implant Communications Systems reliably with very low probability of interference to the Metaids primary users of the band. No unacceptable interference to the Medical Implant Communications System would occur. A preliminary draft new recommendation is annexed hereto.