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Review of Medical Implant Communication System (MICS) band and network[☆]

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Abstract

The Medical Implant Communication System (MICS) is a low-power, short-range (2 m), high-data-rate, 401–406 MHz (the core band is 402–405 MHz) communication network that has been accepted worldwide for transmitting data to support the diagnostic or therapeutic functions associated with medical implant devices. The frequency band is explored to design mobile and comfortable communication systems to support human life. This paper reviews the present situation of MICS devices and summarizes the technical requirements for successful MICS network implementation based on the recommendations published by different frequency management authorities around the world.

Keywords: Medical Implant Communication System (MICS); Implanted device; Body-worn device; Inductive link; Protocol

1. Introduction

Millions of people are affected by heart disease and suffer from chronic diseases such as pain, diabetes, and hypertension. It is important to diagnose a chronic disease early, so that doctors can provide the necessary medical treatment, and patients can change their lifestyles before the condition worsen, thus avoiding more complex and costly treatments. Active implant devices with wireless capabilities can be used to diagnose and provide warnings to support human life. Different implanted devices such as implanted cardiac defibrillators (ICD), pacemakers, neurostimulators, drug pumps, and baclofen pumps have been used in the human body. Control from outside the body is also necessary for different purposes, including, device parameter adjustment (e.g., pacing rate), transmission of stored information (e.g., stored electrocardiogram), and real-time transmission of vital monitoring information for short periods (e.g., cardiac performance during the implant procedure).

An inductive link is the conventional method of providing communication between a programmer/ controller (outside the body) and the implanted device. However, this communication system has several limitations. For example, the maximum separation between the two coils, one inside the body and the other outside the body, must not exceed 6 cm. Therefore, the coil outside the body should be kept close to or in contact with the body. As the data rate is also very low (approximately 100 kbps), data transmission takes a long time. Often, a patient must remain in an uncomfortable position to allow proper communication. In addition, a patient with an implanted device should avoid unwanted activation that may derive from other electrical fields, MRI machines, and mobile communication devices operating in the same environment. Moreover, interference is an important issue in inductive-link-based medical communication systems because of the existence of other communication systems in the same frequency band.

To avoid the limitations imposed by inductive link communication, an universal radio frequency (RF) band of 401–406 MHz, for which the core band is 402–405 MHz, has been proposed for medical implant communication systems (MICSs). This band has good conductivity in the human body,

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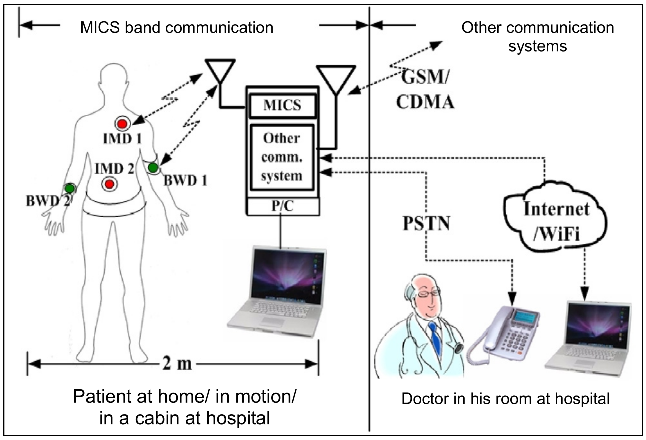

Fig. 1. Complete MICS communication network.

a higher data rate, and a communication range up to 2 m. A MICS network comprises with devices implanted inside a body called as Implanted Device (IMD) or devices put on the body or wearable addressed as body worn device (BWD) and a programmer /controller (P/C). In an MICS network, IMDs perform sensing and therapeutic functions, and the P/C is used to reprogram and send commands to the implanted devices, in addition to collecting data from the implanted devices. The P/C can also communicate with other communication systems, such as the Public Switched Telephone Network (PSTN) or other existing communication systems (e.g., the Internet), for remote control and monitoring of patient condition. A complete network configuration of MICS is shown in Fig. 1. Patients and physicians can monitor the implanted devices within 2 m. Furthermore, the P/C unit can transmit data collected from the implanted devices to a physician's monitoring device with a longer range by employing the existing communication systems. An implant can also receive commands from a health professional via wireless communication links.

A high-level summary of the MICS band has been presented in [1]; this paper covers MICS transceivers, including relevant rules and regulations. In this paper, we present an extensive evaluation of the rules and regulations that have been proposed by different frequency management authorities. We also discuss MICS devices and networks in detail, including the challenges associated with implementation.

2. Brief history of mics band

Since 1980, inductive links have been used for wireless communication between an implanted device and a programmer [2]. A two-coil primary and a secondary with low-frequency transmission were utilized for the activation of an implanted device and data communication. This communication system has several limitations.

In the last decade, a core-band RF frequency of 402–405 MHz with two wing bands of 401–402 MHz and 405–406 MHz was introduced as an MICS band. This band is proposed for use in communication between an IMD or BWD and a P/C for overcoming the limitations of conventional inductive-link-based medical implant communication systems. This band is shared with several other communication devices used in meteorological aids (MetAids), Earth exploration satellites, and meteorological satellites by different countries. In 1998, the International Telecommunication Union (ITU)-R in recommendation SA 1346 [3] proposed sharing of the 401–406 MHz band by both MICS and MetAids.

In July 1999, the U.S. Federal Communications Commission (FCC) proposed the MICS band operating in the 402–405 MHz frequency range to permit use by new ultra-low-power medical implant devices, such as cardiac pacemakers and defibrillators [4]. MICS was proposed as an unlicensed, mobile radio service for transmitting data in support of the diagnostic and therapeutic functions associated with medical implant devices. After this FCC proposal, other countries also considered this band. In October 2003, the Australian Communication Authority (ACA) presented their plan for MICS and related devices [5]. The ACA introduced regulatory arrangements that would support the operation of MICS devices in the 402–405 MHz band on a no-protection, no-interference basis, following the ITU-R recommendation [3] and other international regulatory arrangements. In Australia, the frequency band of 403–405 MHz is used heavily by other services, which may reduce the effective number of channels available for MICS devices in some areas. The operation of medical implant devices in the 403–405 MHz band is allowed to provide harmonization with international arrangements. However, the ACA has avoided the legal technicalities that might arise from such MICS devices entering Australia from overseas, even if only temporarily.

In 2002, The United Kingdom Radio Communications Agency [6] supported the use of MICS in the 402–405 MHz band, similar to the European Radio Communications Committee (ERC) recommendation.

In 2008, at the 5th APT Wireless Forum Meeting, China, Hong Kong, Japan, Korea, Malaysia, New Zealand, the Philippines, and Vietnam agreed to using the frequency band of 402–405 MHz for MICS communication [7] in accordance with the proposal of ITU-R [3].

In 2006, the Electronic Communication Committee (ECC) at the European Telecommunications Standards Institute (ESTI) published a report investigating the coexistence of implanted devices and other devices in the frequency bands of 401–402 MHz and 405–406 MHz [8]. In 2007 [9] and in 2009 [10] ESTI published documents with complete regulations for implanted devices that will use 401–402 MHz and 405–406 MHz, and 402–405 MHz bands, respectively. ESTI defined an IMD or BWD as an ultra-low-power active medical implant (ULP-AMI) and the P/C as an ultra-low-power active medical implant peripheral (ULP-AMI-P). In 2009, the FCC also included an additional two megahertz in the new spectrum in the adjacent "wing" bands at 401–402 MHz and 405–406 MHz [11] for medical implant communication. Altogether, 5 MHz of a contiguous spectrum will be used for advanced wireless medical communication devices on a secondary and non-interference basis. Finally, in February 2010, the Ministry of Industry in Canada proposed the use of the 401–406 MHz band for medical device applications [12].

Table 1
Parameters for MICS network transmitter/MedRadio.

MICS devices	Frequency (MHz)	Authorized maximum channel bandwidth (kHz)	Modulation	Frequency stability	Different transmitters		
					Type 1: Exception to frequency monitoring Low-power, low-duty cycle) (No LBT/AFA)		Type 2: Not exception to frequency monitoring (With LBT/AFA)
					Maximum transmitting power	Duty cycle (Hour basis)	
IMD, BWD, and P/C	401.85–402 (only proposed by FCC [11])	150	FSK [3]	±100 ppm (.01%) for 25 °C to 45 °C (IMD) and 0°C to 55 °C (P/C and BWD)	≤ 25 µW EIRP	≤ 0.1%	
	401–402	100			≤ 250 nW EIRP	≤ 0.1%	≤ 25 µW EIRP
	402–405	300			≤ 100 nW EIRP[a]	≤ 0.01%	≤ 25 µW EIRP
	405–406	100			≤ 250 nW EIRP	≤ 0.1%	≤ 25 µW EIRP

[a] Note for Body-worn Devices
(i) External body-worn operation is limited solely to evaluating the efficacy of a fully implanted permanent medical device that is intended to replace a temporary body worn device,
(ii) FR transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary because of unforeseen circumstances,
(iii) The maximum output power of the temporary body-worn device shall not exceed 200 nW EIRP, and (iv) The temporary body-worn device must comply fully with all other MedRadio rules applicable to medical implant device operation in the 402–405 MHz band.

Table 2
Testing parameters of MICS transmitter.

Transmission power	Equivalent radiated field strength (mV/m) at 3 m from the device	
	Open area test	Free space test such as a fully anechoic test chamber
25 µW EIRP	18.2	9.1
250 nW EIRP	1.8	0.9
100 nW EIRP	1.2	0.6

3. MICS band transmitters

At present, MICS devices are allowed to operate in the frequency band of 401–406 MHz. Some restrictions on the channel bandwidth, output power level, and duty cycle are specified to avoid unexpected interference with other services. Two types of MICS devices are proposed: (i) low-power, low-duty-cycle without Listen Before Talk (LBT)/Adaptive Frequency Agility (AFA), and (ii) high power with LBT/AFA [8,11]. LBT is a frequency monitoring system that is recommended for selecting an available spectrum within the MICS band. The AFA technique should be used to provide the ability to move to the selected frequency for operation. The maximum channel bandwidth for MICS devices is determined as the width of the signal between points on either side of the carrier center frequency that are 20 dB down relative to the maximum level of modulated emission. Table 1 shows the two types of devices and their channel bandwidths, transmission-power limitations, frequency stability, and duty-cycle limitations. The table summarizes the restrictions proposed for MICS devices by the FCC [11], ESTI [9,10], ITU-R [3], and several countries. Only the FCC [11] allows 401.85–402 MHz with higher power and non-LBT to facilitate DexCom's glucose monitoring devices in changing their operating frequency out of the core band (402–405 MHz). The higher power also provides flexibility to other manufacturers designing medical devices in this band.

Before using any MICS device, its radiated emissions and effective isotropic radiated power (EIRP) limits must be tested. The equivalent radiated field strength is tested at 3 m from the MICS devices for different transmission power (i.e., EIRP) levels. The acceptable values are given in Table 2. Testing of an implanted device should be performed in accordance with the FCC approved human body simulator and test technique defined in [13]. The test setup methods for BWDs and P/Cs are explained in the IEEE standard for Methods of Measurement of Radio-Noise Emissions [14].

In an MICS network, the communication medium between a P/C and an IMD consists of air, skin, and fat tissues. It is important to consider the losses due to propagation in the medium when designing an MICS device. A statistical path-loss model for the MICS band is proposed in [15]. IEEE802.15 task group TG6 on body area networks has also adopted this model. The other link parameters such as noise figure, polarization loss, fading loss, noise margin, antenna gain, and SNR should be considered in MICS transmitter/receiver design. Further information about these parameters can be found in the ITU-R recommendation [3].

4. Interference mitigation and safety of MICS network

MICSs share the MICS band with other services, including MetAids, Earth exploration satellites, and meteorological satellites. Earth exploration satellites and meteorological satellites have a communication link from the earth to space, whereas MetAids communicate from space to earth. The MICS receiver may experience interference from the Meteorological transmitters and vice versa. The FCC [4], [11] proposed that an MICS device should not be a source for MetAids; instead, the device must consider interference from MetAids since MICSs use 401–406 MHz band as secondary basis. On the other hand, the medical implant communication link must not be interrupted while monitoring the medical condition of a patient. Therefore, interference mitigation is essential to a successful MICS network. The ITU-R in SA1346 [3] and the ACA [5] show a calculation for the maximum distance between MICS devices and MetAids devices required to minimize interference effects. In addition, ITU-R [3] categorizes interference (impulsive, narrowband, and wideband) and provides methods to mitigate those sources of interference. Impulsive interference can be overcome by either ARQ (automatic request repeat) techniques or FEC (forward error correction) techniques. LBT/AFA could be used for overcoming narrowband interference. A typical transmitted bandwidth for a radiosonde is 300 kHz and at least 10 radiosondes would have to be located within 1 km to jam an MICS network, which is also using the 300 kHz bandwidth. A broadband interferer can make the entire channel (402–405 MHz) unavailable. This case can be mitigated in two ways. One of them is to make the signal strength at the surface of the body approximately 1000 times stronger than that at 2 m. The second approach is to use a low-frequency inductively coupled technology with an MICS transceiver.

In addition to interference mitigation, ensuring patient safety and security are also essential. All data sent to and receive from the implanted device should be correct. MICS devices can use multiple error detection techniques such as those proposed in [3]. First, serial numbers and addresses can be used to identify all communication links. Second, cyclic redundancy codes (CRCs) can be used to validate all transmitted data. Third, a limited valid command set can be used for each operation.

5. Protocols for MICS network

Thus far, there is no specific Medium Access Control (MAC) protocol designed for MICS networks. A MAC protocol is necessary to allow the MICS devices to communicate within other devices in the same band. In order to avoid interference, an MICS device can operate either at low power with a low duty cycle, or at a high power with LBT/AFA. The FCC has proposed several criteria for using the MICS band for devices using LBT/AFA in an MICS network. In the MICS network, only the P/C will have a monitoring system and will initiate the communication session, except any medical implant events (emergency or time-critical data). The monitoring unit of the P/C will check all of the channels within 5 s prior to initiating a communication session to identify a free or least interference channel (LIC). Each channel will be checked for 10 ms. The free channel will be determined by comparing the threshold value calculated using Eq. (1).

$$10 \log B(Hz) - 150(dBm/Hz) + G(dBi) \tag{1}$$

where B is the maximum channel bandwidth and G is the gain of the antenna of a given device. The communication session will use the LIC if any free channel is unavailable. After selecting the free or LIC channel, both P/C and IMD/BWD will switch to the free or LIC channel using the AFA technique. If the communication session is interrupted, there is an optional provision to switch to an alternate channel. The alternate channel is the next possible free channel that is determined during the channel monitoring session. However, before switching to a previously fixed alternate channel, the P/C must check the alternate channel's again for 10 ms. If the P/C finds that the power level is less than the previous power level plus 6 dB, both the P/C and the IMD/BWD will switch to the alternate channel, otherwise not. The communication session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 s.

Medtronic Inc. and Biotronik Inc. have made medical implant devices operating in the MICS band. The details of their protocols have not been disclosed. Meanwhile, many researchers have been using Zigbee for wireless body area network (WBAN) applications. The MAC protocol proposed for WBAN uses carrier sense multiple access/collision avoidance (CSMA/CA), time division multiple access (TDMA), or a combination of CSMA and TDMA. These MAC protocols for WBAN are reviewed in [16] and [17]. IEEE 802.15.6 is still under study for WBAN applications. These activities indicate that a MAC protocol is needed for an MICS network that will follow the rules and restrictions proposed by regulatory authorities when using the MICS band.

6. One way telemetry

In essence, the MICS band supports bi-directional communications. One-way telemetry medical implant systems provide periodic data transfer in one direction, from the implanted device to an external monitoring receiver. These devices are also designed to operate within the 402–405 MHz band, although they typically do not use the adaptive frequency agility (AFA) technique to perform interference mitigation. The operation of one-way telemetry implant devices was initially supported in the U.S.A in April 2000. However, the FCC decided to withdraw this authorization in February 2003 because of interference risk from the transmitters on other services. In the same year, two companies in the USA, Biotronik Inc. and Doxcom, sent requests to the FCC to waive the restrictions on the use of the MICS band for their one-way telemetry devices [18]. In 2004 and 2006, the FCC granted the use of one-way telemetry

Table 3
Data rates for different traffics.

Sensing parameter	Data rate	Reference
Heart rate	1 sample/s or 600 bps	[19]
Medical image	2.4 Mbps	[19]
Blood pressure	1.2 kbps	[20]
Body temperature	1 sample/s to 16 kbps	[19]
Respiratory rate	240–800 bps	[19,20]
SpO_2	32 kbps	[19]
EMG	600 kbps	[19]
EEG	4.2–32 kbps	[19]
ECG	1.2–250 kbps	[19]

on a low power, low-duty-cycle basis at 403.65 MHz (300 kHz) for Biotronik devices and at 402.142 MHz (120 kHz) for Doxcom devices for several years to follow the rules proposed for the use of the MICS band [11].

European regulatory arrangements specifically supporting the use of one-way telemetry implant devices in the 402–405 MHz band have not been established. In the UK, no specific arrangements that would support the use of one-way telemetry implant devices in the MICS band have been made [6]. The ACA has not yet introduced a regulatory arrangement that would support the use of one-way telemetry devices [5]. Thus, one-way telemetry is not typically supported as an MICS band network.

7. Traffic for MICS network

A patient could be monitored at home, while traveling, or at the hospital. The number of parameters that must be monitored depends on the disease that a patient suffers from. For example, when a patient suffers from diabetes, an insulin diffuser could be implanted to monitor blood sugar and to control the sugar level in the blood. Similarly a patient with a heart problem may have a cardioverter-defibrillator implanted to monitor and adjust their heart rate. On the other hand, if a patient is in the intensive care unit (ICU), then different physiological signals, such as blood pressure, temperature, respiratory rate, heart rate, ECG, and EEG are simultaneously monitored. The data rates required for different sensing parameters are showed in Table 3.

Traffic for medical instruments is categorized in three different ways, i.e., constant bit rate (CBR), ON–OFF, and impulsive [19]. Signals for body area network applications are categorized in three different ways, i.e., on-demand, emergency, and normal [21]. In the MICS band, network data transmission from an implanted device must undergo a channel monitoring process and one-way telemetry is not permitted. The P/C must monitor the channel to find a free channel and then, it will initiate a communication session with the implanted device in the free channel, except in the case of a medical implant event (emergency or time-critical data). In this case, the implant devices immediately transmit data without performing any channel monitoring process. Therefore, there are two basic types of traffic in an MICS band, namely, on-demand and emergency.

8. MICS devices and networks

Different companies have been designing medical implant devices, such as Medtronic Inc., Biotronik Inc., St. Jude Medical, Boston Scientific, and Cameron Health. Currently, millions of people are using devices designed by these companies. Several companies are making devices with an inductive link, among which, several use the 2.4 GHz ISM band. Using the MICS RF band, Biotronik Inc. and Medtronic Inc. have developed home monitoring systems that have been used (in the USA and worldwide) [22]. More than 1700 clinics and 150,000 patients are currently benefitting from using the Medtronic CareLink Network. The Concerto cardiac resynchronization therapy-defibrillator (CRT-D) and Virtuoso implantable cardioverter defibrillator (ICD) are the first implantable cardiac devices available with Medtronic's proprietary Conexus^{TM} Wireless Telemetry technology. These devices were developed using the MICS band to enable reliable communication between the implanted device and both clinician programmers and patient home monitoring units at a range of two to five meters.

Zarlink Semiconductor Inc. [23] has made two versions of MICS transceiver (ZL70101 and ZL70102) for the 402–405 MHz band. These devices are commercially available transceivers that are designed to operate in the MICS band. Both devices use a 2.4-GHz ISM link in their wake up circuit. This transceiver allows the user to select from a wide range of data rates by varying the sensitivity, such as 200 kbps (sensitivity <20 μV), 400 kbps (<35 μV), and 800 kbps (<90 μV). To facilitate this flexibility, the system uses either two FSK or four FSK modulations with 200 or 400 ksymbols/s [24], [25]. Zarlink Inc. introduced these transceivers for implanted devices such as pacemakers, ICDs, implanted insulin pumps, bladder control monitors, and implantable physiological monitors. There are several other commercially available transceivers from Texas Instruments and RFM that cover the MICS frequency band. A list of transceivers relevant to our investigation of medical implant communication is shown in Table 4, including their power consumption, data rates, and physical size.

There are ongoing academic projects to develop new MICS devices. For example, Seungkee Min et al. in [26] presented an MICS band binary frequency-shift keying (BFSK) transceiver with a small number of external components, using wake-up receive, normal receive, and transmit modes. The on–off keying (OOK) wake-up receiver sensitivity is −80 dBm at 50 kbps, whereas the BFSK receiver's sensitivity is −97 dBm for a 75 kbps signal and 2 mW power consumption. Other designs such as those in [27–29] present an MICS transceiver architecture with its essential parts, including voltage controlled oscillator (VCO) and FSK modulation. J. Bee et al. [30] designed and implemented an MICS-compatible FSK transceiver using 0.18-μm CMOS technology that consumes 49 μW at a data rate of 250 kbps.

9. Conclusion and future challenges for MICS networks

This work presents a detailed overview of the MICS band and the restrictions imposed on its use. The present situation

Table 4
Comparison of transceivers.

Model and company	Frequency (MHz)	Data rate (kbps)	Max current consumption		Physical chip size (mm ×mm)
			Rx (mA)	Tx (mA)	
CC 1101 (TI)	387–464	0.6–600	14.7	34.4	4.3 × 4.3
CC 1000 (TI)	300–1000	76.8	11.8	26.7	9.6 × 6.4
CC1010 (TI)	300–1000	76.8	9.1	26.6	12 × 12
CC1110 (TI)	391–464	500	16.2	15.2	6.3 × 6.3
ZL70101 (Zarlink)	402–405	800/400/200	5	5	7 × 7
TRC 105 (RFM)	300–510	200	2.7	2.7	5 × 5

of MICS devices and several network issues are discussed. This document will help designers and researchers working in the areas of medical implanted communication and body-area sensor networks; it can provide a quick guideline to designing a safe and reliable medical implant communication system meeting the requirements of the MICS band and the MICS network.

Some challenges exist in the design of a successful MICS network. A low-power reliable MAC protocol to meet the rules and restrictions imposed on the use of the MICS band is essential for simultaneously collecting data from different implanted and body-worn devices. Small-size antenna designs and low-power transceiver designs with high data rates are needed. Moreover, these wireless devices are suggested to implement frequency monitoring capabilities, as specified by the FCC.

Conflict of interest

The authors declare that there is no conflict of interest in this paper.

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