Regulations and Standards for Wireless Medical Applications

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Abstract: *This paper presents current regulations and standards for wireless medical applications within the ITU-R, Canada, and some other countries. It addresses medical implant communications systems, medical telemetry systems, ultra-wideband (UWB) medical radar imaging, the use of various communication networks for telehealth, and the emerging body area sensor networks. The paper addresses data rate and spectrum requirements for some medical applications, and the harmonization of regulations and standards for current and emerging wireless medical devices and networks.*

Keywords: *wireless medical networks, regulations.*

1.0 Introduction

Wireless medical devices and networks operate in several frequency bands under various national and international rules.

The IEEE 802.15 established (2007) Task Group 6 to develop standards for the emerging wireless medical body area networks (BANs) [1, 2]. The FCC proposed (2008) the use of additional spectrum for BANs [3]. In addition, demand on radio spectrum for use in current wireless medical applications is on the increase. This demand is driven by a rapid increase in the use of current medical devices, advancements in wireless technologies, and the need to improve quality, reliability and delivery of healthcare.

This paper presents current and emerging wireless medical devices and networks, and relevant ITU-R regulations. It also presents Canadian regulations and standards and outlines similarities and differences with those of other countries. In addition, this paper discusses data rate and spectrum requirements for some medical applications, as well as the need to harmonize relevant regulations and standards.

2.0 Wireless Medical Applications

Medical Implant Communications Service (MICS): MICS is a mobile service that communicates data from implants (e.g.; defibrillator and cardiac pacemaker) inside a human/animal body to an external device (controller, programmer) for the purpose of performing medical and healthcare functions. No licensing is required for MICS, but equipment must be certified and operated by or under the direction of a physician or a medical professional.

Wireless Medical Telemetry Service (WMTS): WMTS communicates data (except voice and video) related to the remote monitoring of a patient's health. A WMTS system consists of a set of sensors to measure patients' vital signs and other body functions (e.g., pulse and respiration rates) and devices to transmit the data via a radio link to a remote receiver / location.

Body Area Networks (BANs): Wireless BANs are intended to replace wired cables between body (implanted, connected, or worn) sensors and equipment. These networks can provide real-time data for diagnostic and therapeutic purposes

such monitoring health conditions, controlling the delivery of medication, and regulating body functions. A wireless BAN consists of a set of sensors installed in, on or around the patient's body, transmitters and receivers connected to the sensors, and monitoring and control equipment.

UWB Radar Imaging: Sensors that employ UWB technology to detect the location and movement of internal organs and objects inside the body of a human or an animal. The detection accuracy is proportional to the pulse width.

Telehealth: Telehealth refers to the use of communications and information technologies to support telemedicine (diagnostic and therapeutic treatment), telecare, telemonitoring, the exchange of medical information (e.g.; pulse rate, MRI images), medical learning, as well as the management, administration, and exchange of healthcare files. Telehealth is currently using various narrowband and broadband networks not dedicated for medical applications. Mobile and satellite networks are usually used to serve remote areas and areas without sufficient wireline infrastructure or capacity.

3.0 Regulations and Standards

Wireless medical devices and networks usually share the radio spectrum with other wireless services on no-interference no-protection basis. However, a few countries offer protection to specific applications (e.g.; medical telemetry).

The ITU-R Rules

Article **4.4** of the Radio Regulations (RR) allows administrations to introduce domestic rules for applications such as wireless medical devices and networks. The allocation status of frequency bands used or proposed for use by wireless medical systems and networks is given below.

Industrial, Scientific and Medical (ISM) bands: Wireless medical applications are permitted in the following bands as per footnote No. **5.150** of the ITU-R RR: 13 533-13 567 kHz, 26 957-27 283 kHz, 40.66-40.70 MHz, 902-928 MHz in Region 2, 2 400 - 2 500 MHz, 5 725-5 875 MHz, and 24-24.25 GHz.

401 – 406 MHz: The ITU-R RR allocates the band 401 - 406 MHz to the Meteorological Aids Service and the band 401 – 402 MHz to Space Operation (space-to-Earth) Service on a primary basis. In accordance with Recommendation ITU-R SA.1346 MICS is permitted to operate in a portion of the band 401 - 406 MHz at an e.i.r.p. level of -16 dBm (25 microwatts) or less. Interference mitigation techniques should be used by MICS.

2 300 - 2 450 MHz: The ITU-R RR allocates this band in Regions 2 and 3 to the Fixed, Mobile and Radiolocation services on a primary basis, and to the Amateur Radio on a secondary basis. Region 1 allocations are similar with the exception of the Radiolocation status which is secondary. The band 2 360 - 2 400 MHz has been proposed in the US for use by medical BANs [3]. In North America, telemetry stations in the Aeronautical Mobile service have priority over other uses by the Mobile services[1].

UWB: The ITU-R Task Group 1/8 studied UWB (2003-2005) and developed 4 Recommendations (SM.1754 on measurements, SM.1755 on UWB characteristics, SM.1756 on UWB regulations, and SM.1757 on UWB compatibility) as well as a Report (SM.2057) of studies submitted to the ITU-R on UWB compatibility. UWB devices use the radio spectrum on a licence-exempt basis subject to various domestic rules by some national administrations. UWB communications and medical imaging devices use portions of the band 3.1-10.6 GHz.

Regulations in Canada

Wireless medical devices operate in Canada on a licence-exempt (no-interference no-protection) basis provided they meet the requirements set in Radio Standards Specifications RSS-210, RSS-243, or RSS-310 [4]. Equipment operating under RSS-210 and RSS-243 requires certification, while equipment operating under RSS-310 is exempt from certification.

RSS-243 sets the minimum technical requirements for the use of MICS and Medical Implant Telemetry Systems (MITS) in the frequency band 402 - 405 MHz. In addition,

[1] ***5.394*** *In the United States, the use of the band 2 300 - 2 390 MHz by the aeronautical mobile service for telemetry has priority over other uses by the mobile services. In Canada, the use of the band 2 300 - 2 483.5 MHz by the aeronautical mobile service for telemetry has priority over other uses by the mobile services.*

RSS-210 sets the minimum technical requirements for the use of medical telemetry and auditory assistance devices in the following bands: auditory assistance in 72 - 73 MHz, 74.6 - 74.8 MHz, and 75.2 - 76.0 MHz; medical telemetry in 174 – 216 MHz; medical telemetry and auditory assistance in 216 - 216.45 MHz and 216.40 - 217 MHz; and medical telemetry at hospitals and healthcare facilities in 608 - 614 MHz. Any low-power equipment (e.g.; e.i.r.p. ≤ 0.75 mWatts) including medical equipment can also use certain portions of the ISM bands subject to some technical restrictions.

The frequency band 2 360 - 2 400 MHz, which is proposed in the US for use by medical BANs, is currently designated in Canada for the Mobile Aeronautical Telemetry Service as per the Spectrum Utilization Policy SP 2 285 MHz (June 2001), and footnote No. C12 [2] of the Canadian Table of Frequency Allocations [4]. Canada also allows some access in this band to airborne surveillance applications.

Canada is in the process of finalizing domestic rules for wireless devices using UWB technology including the use of UWB medical radar imaging.

Telehealth in Canada is currently using various communication networks, not dedicated for medical use, to provide healthcare in remote and rural areas [5]. However, the telecommunications infrastructure, reliability and service quality continue to present challenges.

The US Regulations

MICS has been permitted since 1999 to operate in the band 402 - 405 MHz. No licensing is required, but equipment must be certified and be operated by a duly authorized healthcare professional. Frequency agility (FA) / listen-before-talk is required for MICS devices. The FCC (2006) granted a waiver to accommodate the Medical Device Radio Communication Service (MedRadio) in the band 401-406 MHz. The FCC allowed the use of low power low duty cycle (LPLDC) MedRadio devices in the bands 401- 402 MHz and 405-406 MHz without the FA requirement. The FCC granted rule waivers for the continued operation of certain LPLDC non-FA devices in the band 402-405 MHz. However, FA is required for MICS devices operating in the core band 402-405 MHz.

In 1973, the FCC authorized the use of 18 channels for low power biomedical Telemetry in the band 460 - 470 MHz on a licensed basis. In 2000, the WMTS was established in the bands 608 - 614 MHz, 1 395-1 400 MHz, and 1 427-1 432 MHz. WMTS has a primary status in 608 – 614 MHz and 1 3 95 - 1 400 MHz. The band 1 427-1 432 MHz is shared by WMTS and non-medical (e.g.; utility) telemetry. Generally, WMTS operations are given a primary status in the band 1 427-1 429.5 MHz, but treated as secondary in the band 1 429.5-1 432 MHz. The FCC rules prohibit home and in vehicles (including ambulances) use of WMTS.

The FCC proposed the use of the bands 401 - 406 MHz and 2 360 - 2 400 MHz for wireless medical BANs on a secondary basis [3]. Telemetry stations in the Aeronautical Mobile Service in the US have a primary status in the band 2 360 - 2 390 MHz and have priority over other mobile services [1].

The FCC authorized (2002) the use of UWB communication and radar imaging systems in the band 3.1-10.6 GHz. The operation of UWB medical imaging systems requires NTIA coordination and restricted to be at the direction of, or under the supervision of a duly licensed healthcare practitioner.

The FCC has initiated a pilot funding program for the creation of a nationwide broadband network dedicated to healthcare, connecting public and private non-profit healthcare providers in rural and urban areas. The FCC has also made telecommunications rates for public and non-profit rural healthcare providers nearly the same as those paid in urban areas.

Manufacturers are also marketing medical devices that operate on a licence-exempt basis (FCC Part-15 rules) in the following bands: 9-315 kHz, 218-222 MHz, 293-320 MHz, 410-450 MHz, 512-518 MHz (TV Channels 14-36), 614-688 MHz (TV channels 38-46), and ISM bands 13.553-13.556 MHz, 902-928 MHz, 2 400 - 2 483.5 MHz, and 5 725 - 5 875 MHz.

[2] ***C12 (CAN-03)*** *The band 2 360 - 2 400 MHz is designated for Mobile Aeronautical Telemetry Service (MATS) applications. The Government of Canada has priority on the use of this band. Access to spectrum by other entities for MATS may be permitted subject to coordination with the Government of Canada systems.*

Regulations in Europe

Europe (ETSI) has developed standards for medical implants that communicate to an external device to allow them to be controlled by qualified medical practitioners in the following bands: inductive loop ultra low power (ULP) active medical implants in 9-315 kHz; ULP animal implant devices in 315-600 kHz and 12.5 -20 MHz; ULP animal implant membrane devices in 30-37.5 MHz; ULP MICS and accessories in 401- 402 MHz, 402-405 MHz, and 405 - 406 MHz.

Europe has developed standards for in-ear monitoring devices. Europe has considered the bands 608 - 614 MHz, 1 395 - 1 400, and 1 429 - 1 432MHz and decided not to use them for WMTS because of their use by other communication services. Europe has also developed standards for UWB communication and measurement devices in 2006.

Telehealth/e-Health standards are being studied in the ETSI e-Health Project. The European Commission also launched (2008) Healthware "standard and interoperable satellite solutions to deploy health care services over wide area" to serve geographical areas without sufficient terrestrial telecommunication capacities for interactive health services.

Regulations in Other Countries

In Japan, MICS operates in the band 401 - 405 MHz, and WMTS in the bands 420 - 429 MHz and 440 - 449 MHz. Japan allows the indoor use of UWB communication devices on a licence-exempt basis (2005).

In New Zealand and Australia, MICS uses portions of the band 401-406 MHz. There is a variety of WMTS allocations in both countries that do not align. Australia (April 2004) granted an interim licence for UWB ground penetrating radar, and extended its rules to allow other radar imaging devices to be licensed for testing, pilot marketing, and demonstration (December 2004). New Zealand (September 2005) issued an interim licensing arrangements, which granted radio licences to UWB radar imaging devices with low potential to cause interference on a case-by-case basis.

4. Discussion

MICS: MICS operates globally in parts of the band 401 - 406 MHz on a licence-exempt basis (Rec. ITU-R SA.1346). For example, MICS operates in the band 402-405 MHz in more than 50 countries including Canada, US, Europe, and Japan where FA is required. Some medical technology product companies have requested to waive the FA requirement for the core MICS band 402 - 405 MHz and requested additional spectrum for medical data in 401 - 402 MHz and 405 - 406 MHz. As a result, Europe and the US have expanded MICS into the bands 401 - 402 MHz and 405 - 406 MHz.

Thus there is a need for international cooperation to: 1) Harmonize medical data / MICS expansion into the bands 401-402 MHz and 405-406 MHz as well as to study the potential introduction of BANs into 401-406 MHz; 2) Develop rules for animal medical implants recognizing that Europe has adopted standards for ULP animal implants in the bands 315 -600 kHz, 12.5-20 MHz, and 30-27 MHz; 3) Develop rules for inductive loop implants recognizing that Europe has adopted standards for inductive loop ULP active implants in 9-315 kHz. The FCC has also sought comments on whether medical implants that use inductive signal coupling should be permitted in the band 90-110 kHz (FCC 06-103).

WMTS: The service status of WMTS (primary / secondary, etc.) and its frequency bands are not harmonized globally or regionally. For example, the frequency band 608 - 614 MHz is used for WMTS on a licence-exempt basis in Canada but on a primary licensed basis in the US. In addition, Europe decided not to use this band for WMTS because of its use by other radiocommunication services. In addition, the FCC reallocated (2000) the former government bands 1 395 - 1 400 MHz and 1 429 - 1 432 MHz for WMTS. Europe has considered these bands for WMTS and decided that they would not be available. In Canada the band 1 429.5 - 1 430.5 MHz is used (RSS-142) for non-medical utility telemetry and narrowband Multipoint Communications Systems. WMTS service status and the harmonized use of WMTS frequency bands need to be addressed internationally.

BANs: The IEEE 802.15.6 is developing standards for low power wireless medical BANs [1, 2]. Wireless medical BANs could operate in

the MICS, ISM, and in the UWB 3.1-10.6 GHz frequency bands [1-3]. The FCC also proposed (April 2008) the use of the band 2 360 - 2 400 MHz for BANs. The IEEE 802.15.6 has supported the FCC proposal (May 2008). Medical imaging and some healthcare applications could generate huge amounts of data (hundreds of megabytes) and would require high speed links. However, data rates from vital sign sensors are much lower, from a few kbit/s to several Mbits/s, as shown below [6].

Sensor Type	Throughput (kbits/s)
Glucose	0.01 - 0.1
SpO2	0.01 - 0.1
Blood Pressure	0.01 10
ECG	10-100 (12 bit, 300Hz, x 20)
EEG	10-200 (6 kbps x 32)
EMG	10-1500 (16-bit, 8kHz, x12)

Different wireless technologies could meet the data rate and operational requirements of BANs and medical imaging. However, UWB has several advantages when high data rate, low power / low specific absorption rate (SAR), high quality links (PER < 10^-8), privacy, low cost (disposable sensors), and accurate positioning of staff and equipment are required [2, 6, 7].

UWB Radar Imaging: UWB medical radar imaging devices are slowly entering the marketplace. Several countries (US 2002, Singapore 2003, Australia 2004, New Zealand 2005, Hong Kong 2005, Japan 2005, Europe 2006, and South Korea 2006) have adopted domestic UWB rules that permit medical imaging devices in portions of the band 3.1 - 10.6 GHz. These rules are not harmonized.

Telehealth: There is no global or regional harmonization of telehealth wireless standards and rules. Telehealth currently uses various wire-line and wireless networks which also lack the level of security and privacy required for communicating personal and medical information. The delivery of telehealth to remote and rural areas, the outsourcing of pharmacies, real-time tele-consulting, and multimedia medical content would require high-quality, high-reliability and high-speed wireless networks. In December 2007, the ITU-T SG17 decided to include telemedicine in its next study period. Thus it is worth addressing wireless telehealth issues within the ITU-R. There is a need to address the use of dedicated spectrum bands for telehealth, and to globally harmonize speed requirements, regulations and standards.

5. Summary

Patients travel internationally and often carry and use medical devices across national borders, thus global harmonization of rules and standards is essential. The frequency bands, service status (level of protection), technical standards and certification requirements of current wireless medical devices and networks are not harmonized globally or regionally. In addition, the introduction of BANs and the use of dedicated spectrum for some medical applications (e.g.; telehealth) need to be standardized and harmonized internationally. Harmonization will benefit the user, the wireless medical industry, and regulators. It will also impact positively on cost-saving, quality, reliability and delivery of healthcare.

Some wireless medical devices and systems are life-supporting and life-saving applications which may require secure, high-quality, and high reliability links. Different wireless technologies could meet the speed and operational requirements of wireless medical applications. However, the IEEE 802.15.6, academics, and researchers working on BANs are focusing on UWB when high data rate, accurate positioning, low-power consumption, low exposure to RF radiation, real-time, and privacy are required.

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