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Active Medical Implants Operating in the 402-405 MHz Band

Preface

Radio Standards Specification 243, Issue 2, *Active Medical Implants Operating in the 402-405 MHz Band*, sets out the minimum certification requirements for devices using new and emerging technologies for medical applications including:

- external transceivers (programmers/controls) that incorporate frequency agile interference avoidance systems and transceivers internal to the human body (active medical implants) that radiate radio frequency energy from within the human body; and
- external receivers that rely on single-frequency, low duty cycle, redundant-code repetitive-transmission interference avoidance systems and transmitters internal to the human body (active medical implants) that radiate radio frequency energy from within the human body.

RSS-243, Issue 2, must be used in conjunction with RSS-Gen, *General Requirements and Information for the Certification of Radiocommunication Equipment*, for general specifications and information relevant to the equipment for which this Standard applies.

This document will be in force as of the publication date of *Canada Gazette* notice SMSE-012-05, after which the public has 90 days to make comments. Comments received will be taken into account and a new issue, or a revised version of this issue may be developed.

Issued under the authority of
the Minister of Industry

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1. Scope

This Radio Standards Specification (RSS) sets out the minimum requirements for the certification of transmitters and receivers used in radiocommunication systems which provide medical implant communication in the 402-405 MHz band, namely the Medical Implant Communication System (MICS) and the Medical Implant Telemetry System (MITS). These devices are defined as Category I equipment as per RSS-Gen.

MICS is used to provide transmission of data for the purpose of facilitating diagnostic and/or therapeutic functions associated with communication between an external medical implant programmer/controller transceiver or receiver and implanted medical device(s) or between implanted medical devices.

MITS is used to provide transmission of data on a periodic basis (non-medical event related). MITS operate in the 403.5-403.8 MHz band and shall only provide one-way, non-voice digital communications from an active medical implant transmitter to an external receiver.

2. General Information

Devices certified under this Standard are classified as Category I equipment and a technical acceptance certificate (TAC), issued by the Certification and Engineering Bureau of Industry Canada or, a certificate issued by a recognized Certification Body (CB), is required.

Devices covered by this standard produce very low emission levels such that they can co-exist with the primary radio services, namely the meteorological aids service.

Active medical implant devices operate in the 402-405 MHz band under the secondary mobile service on a "no-interference, no-protection" basis with respect to the primary meteorological aids service.

2.1 Licensing Requirements

Medical radiocommunication systems covered by this standard are licence-exempt.

2.2 Related Documents

The following documents should be consulted:

ETSI EN 301 839-1

*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*

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.

2.3 Definitions

The following terms and definitions apply to this standard:

Access protocol is a specification for measuring natural and man-made ambient background levels for the purpose of providing a technique for spectrum access that reduces the potential for harmful disturbance to/from other users of the spectrum.

Active medical implant is a diagnostic or therapeutic device used for the human body containing a power source and a transmitter or transceiver for the purpose of providing a one-way or two-way digital communications link.

Channel Bandwidth is any continuous segment of spectrum used for a communication transmission.

Dedicated antenna is a permanently attached or removable antenna supplied and certified with the radio equipment, designed as an indispensable part of the equipment.

Emission bandwidth is, for the purposes of this document, defined in ETSI EN 301 839-1.

Integral antenna is a permanent fixed antenna designed as an indispensable part of the equipment.

Least Interfered Channel (LIC) is the channel, among the available channels, which has the lowest potential for causing disturbance to, or receiving disturbance from, other users of the band. The LIC is determined by measuring the level from both natural and man-made signal sources in available channels and selecting the channel with the lowest measured ambient power level that is above the calculated maximum permissible threshold-power level.

Listen Before Talk (LBT) is a performance requirement, usually in the form of a protocol that requires a communications system to determine if the channel it intends to communicate in is occupied by another user, and selects from the available spectrum a channel for communication that reduces, to the extent possible, the potential for interference to/from another user of the spectrum.

Medical Implant Communication System (MICS) is a system specifically for the purpose of providing two way non-voice digital communications between an external programmer/control transceiver and an active medical implant transceiver or between active medical implant transceivers placed in the human body.

Medical implant communication system channel is any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MICS communications session.

Medical implant communication system session is a collection of transmissions that may or may not be continuous, between co-operating medical implant devices and accessories, including programmers/controls transferring patient related information.

Medical implant device is an apparatus that includes a transmitter or transceiver that is placed inside the human body for the purpose of performing diagnostic functions and/or the delivery of therapeutic treatment.

Medical implant event is an occurrence or, the lack of an occurrence, recognized by a medical implant device or duly authorized health care professional that requires the immediate transmission of data from a medical implant transmitter in order to protect the safety of the person in whom the medical implant transmitter has been placed.

Medical implant programmer/control transmitter is a transmitter or transceiver, operating outside of a human body that is designed to monitor the channel or channels the MICS devices intend to occupy, by selecting a communications channel for a link to a medical implant transmitter based on the use of the LBT access protocol and by transferring information to/from the implant after initiating the communications link.

Medical implant transmitter is a transmitter or transceiver which is designed to be placed within a human body for the purpose of providing digital communications.

Medical Implant Telemetry System (MITS) is a system which provides one-way, non-voice digital communications between an external receiver and an active medical implant transmitter.

Monitoring system is the circuitry in a medical implant transmitter or an associated programmer/control transmitter that assures conformity with LBT spectrum access protocol requirements.

Monitoring system bandwidth is the overall bandwidth of the system used to measure the level of ambient and man-made signals in the channel the transmitter or transmitters associated with the monitoring system intend to use during a medical implant communications session in a LBT system.

Threshold power level is the ambient signal power level in an LBT system above which the monitoring system shall select spectrum for use in a MICS communication session according to the next available channel with the lowest level of ambient signal power or least interfered channel (LIC).

3. Measurement Methods

3.1 General Information

In addition to the requirements of RSS-Gen, the following apply:

- (a) For the purposes of this and the following sections, measurements on one frequency near the middle of the 402-405 MHz band are considered sufficient to demonstrate compliance with the provisions of this RSS.

- (b) The pertinent definitions of ETSI EN 301 839-1 apply when conducting measurements. The measurement methods prescribed in this Standard are considered to be equivalent to the measurements made as per the most recent version of ETSI EN 301 839-1.
- (c) Equipment intended to be implanted in the human body shall be tested in a simulated human torso in order to replicate operation of the implant under actual operating conditions. Please refer to Annex A of ETSI EN 301 839-1 for further information.

3.2 Occupied Bandwidth

The occupied (emission) bandwidth measurement method outlined in RSS-Gen shall be used.

3.3 Frequency Stability

In addition to the requirements of RSS-Gen, the following temperatures and supply voltage ranges apply:

- (a) For external devices:
 - (i) normally used outdoors, at temperatures of -30°C , $+20^{\circ}\text{C}$ and $+50^{\circ}\text{C}$, and at the manufacturer's rated supply voltage;
 - (ii) normally used indoors, at temperatures of 0°C , $+20^{\circ}\text{C}$ and $+50^{\circ}\text{C}$, and at the manufacturer's rated supply voltage; and
 - (iii) when the temperature is at $+20^{\circ}\text{C}$, at $\pm 10\%$ of the manufacturer's rated supply voltage.

- (b) For internal devices:

at temperatures of $+25^{\circ}\text{C}$, $+37^{\circ}\text{C}$, and $+45^{\circ}\text{C}$, and at the manufacturer's rated operating voltage using a new battery only.

If the frequency stability limits are only met at a different temperature range than those specified in (i) and (ii) of (a), or in (b), the frequency stability requirement will be deemed met if the transmitter is automatically inhibited from operating outside this different temperature range and the published equipment operating characteristics are revised to reflect this different temperature range.

3.4 Transmitter Unwanted Emissions

In addition to the requirements of RSS-Gen, unwanted emissions of transmitters intended to be implanted into the human body shall be measured as per Section 3.1(c).

3.5 Receiver Spurious Emissions

In addition to the requirements of RSS-Gen, spurious emissions of receivers intended to be implanted in the human body shall be measured as per Section 3.1(c). As an alternative, the conducted measurement

method may be used when the antenna is detachable. In such a case, the receiver spurious signal may be measured at the antenna port.

3.6 Monitoring System Measurements

Manufacturers of MICS operating in the 402-405 MHz band shall share the spectrum on an equal basis in order to protect the health and safety of the patients these systems are designed to serve. To accomplish this goal, medical implant programmer/control transmitters shall incorporate a mechanism for monitoring the spectrum that the MICS devices intend to occupy.

In the case where an individual has two or more implanted devices, and medical implant to medical implant communications is provided for without the use of a programmer/control to monitor the spectrum, the communications session shall be under the control of an implant capable of monitoring the spectrum, using the access protocol specified below, that the MICS devices intend to occupy.

The methods to measure the monitoring requirements of MICS are outlined in the most recent version of ETSI EN 301 839-1.

Specifically, the following parameters shall be measured:

- (a) system threshold power levels;
- (b) monitoring system bandwidth and emission bandwidth;
- (c) scan cycle time;
- (d) minimum channel monitoring;
- (e) channel access using either the threshold level concept with LIC or LIC only as utilized by the equipment under test (EUT);
- (f) discontinuation of a MICS session; and
- (g) use of pre-scanned alternate channel.

4. User Manual

The user manual for all transmitters covered by this Standard shall contain the following statement in a conspicuous location:

“This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.”

5. Transmitter and Receiver Standard Specifications

5.1 Channelling Arrangement

MICS devices shall be designed to operate on a minimum of nine channels equally spaced across the 402-405 MHz band. MITS devices shall be designed to operate on a single frequency in the 403.5-403.8 MHz band.

The maximum channel bandwidth permitted is 300 kHz.

For Time Division Duplex (TDD) systems, the emission bandwidth of the device with the largest bandwidth is regarded as a MICS channel.

For Frequency Division Duplex (FDD) systems, the aggregate spectrum is the sum of the individual emission bandwidth of each device participating in the MICS communications session.

5.2 Types of Modulation

Equipment certified under this Standard shall use digital modulation. Transmission of digitized or analogue voice communication is prohibited.

5.3 Frequency Stability

The carrier frequency shall not depart from the reference frequency in excess of ± 100 parts per million.

5.4 Transmitter Output Power

The maximum average e.i.r.p. for MICS transmitters shall not exceed a value of 25 microwatts.

The maximum average e.i.r.p. for MITS transmitters shall not exceed a value of 100 nanowatts.

5.5 Transmitter Unwanted Emissions

- (a) Emissions more than 250 kHz outside of the 402-405 MHz band shall not exceed the field strength limits specified in Table 1.

Table 1 – Field Strength Limits for Transmitter Unwanted Emissions

Frequency (MHz)	Field Strength (microvolt/m at 3 metres)
30-88	100
88-216	150
216-960	200
960 and above	500

- (b) Emissions within the 402-405 MHz band which are more than 150 kHz away from the centre frequency of the spectrum the transmission intends to occupy and up to 250 kHz above and below the band shall be attenuated at least 20 dB below the maximum transmitter output power.

5.6 Receiver Spurious Emissions

Receiver spurious emissions shall comply with the limits specified in RSS-Gen.

5.7 Monitoring System Specifications for MICS

The requirements of Section 5.7 do not apply to MITS.

5.7.1 System Threshold Power Levels

The monitoring threshold power level shall not be greater than the calculated level given by the equation, $10 \log_{10} B \text{ (Hz)} - 150 \text{ (dBm/Hz)} + G \text{ (dBi)}$, where B is the emission bandwidth of the MICS communication session transmitter having the widest emission bandwidth and G is the antenna gain of the medical implant programmer/control transmitter monitoring system, relative to an isotropic antenna.

5.7.2 Monitoring System Bandwidth

The monitoring system bandwidth measured at its 20 dB down points shall be equal to, or greater than the emission bandwidth of the intended transmission.

5.7.3 Scan Cycle Time

Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer/control transmitter shall monitor all the channels in the 402-405 MHz frequency band.

5.7.4 Minimum Channel Monitoring Period

Each MICS channel shall be monitored for a minimum of 10 milliseconds during each scan cycle of 5 seconds or less.

5.7.5 Channel Access

Immediate access is permitted on any channel having an ambient power level that is below the maximum threshold. If no channel having an ambient power level below the maximum threshold is available, the equipment under test shall access and transmit on the least interfered channel (LIC).

5.7.6 Discontinuation of a MICS Session

MICS shall cease transmission in the event the communications session is interrupted for a period of 5 seconds or more.

5.7.7 Use of the Pre-scanned Alternate Channel

The pre-scanned alternate channel, selected at the time the channel of operation is initially selected, may be accessed in the event a communications session is interrupted by interference. Before transmitting on this alternate channel, the following criteria shall be met:

- (a) the channel shall be monitored for a period of at least 10 milliseconds;
- (b) the detected power level during this 10 millisecond, or greater monitoring period, shall not exceed 6 dB above the power level detected when the channel was chosen as the alternate channel; and
- (c) in the event that this alternate channel provision is not used by the MICS, or if the criteria in (a) and (b) are not met, another channel shall be selected using the access criteria in 5.7.1 to 5.7.6 above.

5.8 Other MITS Specifications

For the purposes of this Standard the duty cycle is defined as the ratio, expressed as a percentage, of the maximum transmitter “on” time on one carrier frequency, relative to a one-hour period.

The duty cycle shall be limited to 0.01% of an hour and the number of transmissions shall not exceed 10 in any given hour.