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Medical Devices Operating in the 401-406 MHz Frequency Band

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Preface

Radio Standards Specification 243, Issue 3, *Medical Devices Operating in the 401-406 MHz Frequency Band*, sets out the minimum certification requirements for active Medical Implant Communications Service (MICS) devices, which include Medical Implant Telemetry System (MITS) and Medical Data Service (MEDS) devices using new and emerging technologies for medical applications.

This new version will be in force as of the publication date of Notice SMSE-001-10 in *Canada Gazette*, Part I. Upon publication, the public has 120 days to submit comments. Comments received will be taken into account in the preparation of the next version of the document.

Listed below are the changes:

1. Allowing blood glucose monitoring MICS transmit-only devices without insulin injection capabilities and without Listen Before Talk operating at the center frequency 402.142 MHz to be certified under specific technical requirements until March 20, 2013.

2. Introducing MEDS in the 401-402 MHz and 405-406 MHz frequency bands, which include medical implants and medical body-worn devices.

Issued under the authority of
the Minister of Industry

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Contents

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 active Medical Implant Communication System (MICS), which includes Medical Implant Telemetry System (MITS) and Medical Data Service (MEDS) in the 401-402 MHz and 405-406 MHz bands. These devices are defined as Category I equipment as per RSS-Gen.

MICS devices communicate data[1] for the purpose of facilitating diagnostic and/or therapeutic functions associated with communication between an external medical implant programmer/controller transceiver or receiver and an implanted medical device(s), or between implanted medical devices.

MITS provides 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.

MEDS devices communicate data from single or multiple sources, one of which is an active medical implant or a body-worn sensor, for the purpose of facilitating diagnostic patient evaluation, data readout, data storage or therapeutic functions. MEDS devices are not intended to be used to communicate time-critical data.

2. General Information

RSS-243, Issue 3, 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.

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 and MEDS devices subject to this standard operate under the secondary mobile service on a “no-interference, no-protection” basis with respect to the meteorological aids service.

No antenna for a transmitter certified under this standard shall be configured for permanent outdoor use.

All medical devices certified under this standard shall be subject to the radiofrequency radiation exposure requirements specified in RSS-102.

[1] Life critical applications are encouraged in the core MICS 402-405 MHz band.

2.1 Licensing Requirements

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

2.2 Related Documents

ETSI EN 301 839-1	*Electromagnetic compatibility and Radio Spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods*
ETSI EN 302 537-1	*Electromagnetic compatibility and Radio Spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods*
ITU- R Recommendation RS.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/Protocole d'accès 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/Implant medical actif is a diagnostic or therapeutic device containing a power source (e.g. electrical energy or any source of power other than that directly generated by the human body or gravity) and a transmitter or transceiver for the purpose of providing a one-way or two-way digital communications link.

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

Body-Worn Medical Device (BWMD/Dispositif médical porté sur soi (DMPS) is a medical sensor, handheld device, or other medical device intended to be operated in close proximity to the human body (6 cm or less from the skin surface), and is used to sense and/or transfer, via means of radio frequency transmission, human physiological parameters or system programming information.

Communication channel/Voie de communication is any continuous segment of radio spectrum used for a communication transmission.

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

Emission bandwidth/Largeur de bande d'émission is measured as the width of the signal between the points on either side of the carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier.

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

Least Interfered Channel (LIC)/Canal le moins brouillé 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)/Contrôle avant communication 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 Data Service (MEDS/Service des données médicales (SDM) is a service that uses a system specifically for the purpose of providing non-voice digital communications between active medical implants and/or body-worn devices and other devices external to the human body that are engaged in transferring non-time critical individual patient-related physiological information. Implantable devices, with or without frequency agility, are permitted in the 401-402 MHz and 405-406 MHz bands.

MEDS programmer/control transmitter/Émetteur programmeur/contrôleur d'implants du SDM is a transceiver that is designed to monitor the channel or channels the MEDS system devices intend to occupy, by selecting a communications channel for a link to a medical implant or body-worn medical device transmitter, based on the use of the LBT access protocol and by transferring information to/from the MEDS system devices after initiating the communications link.

MEDS system/Système SDM is a collection of medical devices having short-range RF transmitting capability that are associated with a specific patient, consisting of at least one active medical implant or body-worn device, together with other devices external to the body, that have the ability to communicate with each other using frequencies in the 401-402 MHz and/or 405-406 MHz bands.

MEDS system communication link (MEDSCL)/Liaison de communication du SDM (LCSDM) is a collection of transmissions which may or may not be continuous, between MEDS system devices, including at least one active medical implant or body-worn device together with other devices external to the body, engaged in transferring non-time critical patient-related physiological information collected by a single MEDS system.

MEDS system communication channel/Canal de communication du SDM 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 MEDS session.

MEDS device/Dispositif du SDM is any ultra-low-power medical device transmitting in the 401-402 MHz and/or 405-406 MHz band. Only two types of MEDS system devices are permitted under the present document:

(1) frequency agile devices designed to access a minimum of 18 channels evenly distributed across the 401-402 MHz and 405-406 MHz bands with a minimum of 9 channels defined for each 1 MHz segment (i.e. 401-402 MHz and 405-406 MHz); and

(2) devices capable of operation only on a single channel using low duty cycle and low power for spectrum access in the 401-402 MHz or 405-406 MHz bands.

Medical Implant Communication System (MICS)/Système de communication d'implants médicaux (SCIM) is a system operating in the 402-405 MHz band 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.

MICS channel/Canal du SCIM 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.

MICS system session/Session du SCIM 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.

MICS device/Dispositif du SCIM is a medical device operating in the 402-405 MHz band that includes a transmitter or transceiver that is totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice for the purpose of performing diagnostic functions and/or the delivery of therapeutic treatment. The following types of devices are permitted under the present document:

(1) frequency agile devices designed to access a minimum of 9 channels evenly distributed across the 402-405 MHz band;[2] and

(2) non-frequency agile transmit only MITS devices in the 403.5-403.8 MHz band.

Medical implant event/Incident d'implant médical 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.

[2] Blood glucose monitoring MICS transmit-only devices without insulin injection capabilities and without LBT that meet specific technical requirements (see Sections 5.1 and 5.7) and operate at the center frequency 402.142 MHz are allowed to be certified until March 20, 2013.

MICS programmer/control transmitter/Émetteur programmeur/contrôleur d'implants médicaux 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/Émetteur d'implant médical 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)/Système de télémesure par implant médical (STIM) is a system which provides one-way, non-voice digital communications between an external receiver and an active medical implant transmitter.

Monitoring system/Système de monitorage is the circuitry in a medical implant transmitter, body-worn medical device or an associated programmer/control transmitter that assures conformity with LBT spectrum access protocol requirements.

Monitoring system bandwidth/Largeur de bande du système de surveillance 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 an LBT system.

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

Time-critical data/Données critiques is data which, if not transferred immediately, will result in compromising the health and/or safety of the patient.

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 each band of operation (401-402 MHz, 402-405 MHz, 405-406 MHz) are considered sufficient to demonstrate compliance with the provisions of this RSS.

(b) 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 or ETSI EN 302 537-1. The pertinent definitions in ETSI EN 301 839-1 (402-405 MHz) and ETSI EN 302 537-1 (401-402 MHz and 405-406 MHz) apply when conducting measurements.

(c) Equipment intended to be implanted or worn on the human body shall be tested in a simulated human torso in order to replicate operation of the device under actual operating conditions. For further information, please refer to Annex A of ETSI EN 301 839-1 for MICS band devices, and ETSI EN 302 537-1 Annex A for MEDS band devices as applicable.

3.2 Occupied Bandwidth

The occupied 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°C and +50°C, and at the manufacturer's rated supply voltage;

(ii) normally used indoors, at temperatures of 0°C, +20°C and +50°C, and at the manufacturer's rated supply voltage; and

(iii) when the temperature is at +20°C, at ± 10% of the manufacturer's rated supply voltage.

(b) For internal and body-worn medical devices:

(i) at temperatures of +25°C, +37°C and +45°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 from 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 in or worn on 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 or worn on 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 a minimum of 9 channels evenly distributed across the MICS band. The channel selected for operation must have an ambient noise level below the threshold level for the system or be the channel with the lowest ambient noise level.

Similarly, manufacturers of MEDS device operating in the 401-402 MHz and/or the 405-406 MHz bands 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, any device having an e.i.r.p. above 250 nanowatts must be operating under the control of a programmer/control transmitter that incorporates a mechanism for monitoring a minimum of 18 channels evenly distributed across the MEDS bands. The channel selected for operation must have an ambient noise level below the threshold power level for the system or be the channel with the lowest ambient noise level. However, MEDS devices operating in the 401.85-402 MHz are not required to have a mechanism for monitoring (i.e. LBT) provided that the transmit power is not greater than 25 microwatts, the duty cycle does not exceed 0.1% and has a maximum limit of 100 communication sessions per hour (see Section 5.8).

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

The measurement methods used to determine compliance with the monitoring requirements of MICS band devices are outlined in the most recent version of ETSI EN 301 839-1.

The methods to measure and determine compliance with the monitoring requirements for MEDS band devices are outlined in the most recent version of ETSI EN 302 537-1.

Specifically, the following parameters shall be measured:

(a) system threshold power levels and system ability to measure signals below this threshold level;

(b) monitoring system bandwidth and emission bandwidth;

(c) scan cycle time;

(d) minimum channel monitoring time;

(e) channel access using LBT and either the threshold level concept with LIC or LIC only, as utilized by the equipment under test (EUT) (see (a) above);

(f) discontinuation of a MICS session; and

(g) use of pre-scanned alternate channel (if applicable).

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 9 channels evenly spaced across the 402-405 MHz band. Blood glucose monitoring MICS transmit-only devices without insulin injection capabilities that lack such frequency agility and can operate on only one channel of less than 150 kHz centered at 402.142 MHz, may nevertheless be certified until March 20, 2013[3] provided they operate at a power level of less than 10 microwatts e.i.r.p. and with a total duty cycle of 0.005% or less. MITS devices shall be designed to operate on a single frequency in the 403.5-403.8 MHz band. MEDS devices shall be designed to operate on a minimum of 18 channels evenly distributed across the 401-402 MHz and 405-406 MHz bands if their e.i.r.p. is above 250 nanowatts. MEDS Low Power Low Duty Cycle (LPLDC) devices in the 401-401.85 MHz or 405-406 MHz are permitted to operate on only a single channel if their e.i.r.p. is below 250 nanowatts.

The maximum channel bandwidth permitted is 300 kHz for MICS band devices, 150 kHz for the MEDS band devices operating in 401.85-402 MHz, and 100 kHz[4] for MEDS band devices operating in the 401-401.85 MHz or 405-406 MHz. Lesser bandwidths down to 25 kHz are permitted for any device.

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

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[3] After March 20, 2013, these blood glucose monitoring MICS transmit-only devices shall not be manufactured, imported, distributed, leased, offered for sale or sold in Canada. However, patients may continue to use such devices obtained prior to March 20, 2013.

[4] It is permitted to aggregate 25 kHz segments up to a maximum of 100 kHz for each channel bandwidth.

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 is 25 microwatts.

The maximum average e.i.r.p. for MITS transmitters is 100 nanowatts.

The maximum average e.i.r.p. for MEDS transmitters operating in a system that uses LBT for channel selection is 25 microwatts.

The maximum average e.i.r.p. for MEDS transmitters in 401-401.85 MHz or 405-406 MHz that do not operate in a system that uses LBT for channel selection is 250 nanowatts.

The maximum average e.i.r.p. for MEDS transmitters in 401.85 -402 MHz that do not operate in a system that uses LBT for channel selection is 25 microwatts.

Note: Refer to the applicable ETSI standard for measurement requirements for transmitter power.

5.5 Transmitter Unwanted Emissions

(a) Emissions from MICS devices 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 MICS 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
Note: At band edges, the tighter limit applies.	

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

(c) Emissions from transmitters designed to operate in the MEDS shall be attenuated in accordance with the following:

(1) Except for emissions into the MICS band (402-405 MHz), emissions more than 100 kHz outside of the MEDS bands (401-402 MHz and 405-406 MHz) shall be attenuated to a level no greater than the following field strength limits:

Table 2 – Field Strength Limits for MEDS 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
Note: At band edges, the tighter limit applies.	

(2) Emissions in the MICS band (402-405 MHz) shall be attenuated to a field strength level of 100 microvolt/m at 3 meters.

(3) Emissions from a MEDS transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(4) Emissions from a MEDS transmitter (401-402 MHz and 405-406 MHz) more than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20 dB, except as noted in (1) and (2) above for emissions into the 402-405 MHz band. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function, with an instrument resolution bandwidth approximately equal to 1 percent of the emission bandwidth of the device under measurement.

(5) Emissions 100 kHz or less above 406 MHz and below 401 MHz must be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function, with an instrument resolution bandwidth approximately equal to 1 percent of the emission bandwidth of the device under measurement.

(d) Emission limits shown in (a), (c)(1) and (c)(2) above are based on measurements employing a CISPR quasi-peak detector, except that, above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz.

5.6 Receiver Spurious Emissions

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

5.7 Monitoring System Specifications for MICS and MEDS

The requirements of Section 5.7 do not apply to MITS or MEDS devices operating in 401-401.85 MHz or 405-406 MHz with a maximum e.i.r.p. of 250 nanowatts or less. The

requirements of Section 5.7 do not apply to blood-glucose monitoring MICS transmit-only devices operating at a center frequency of 402.142 MHz that are certified prior to March 20, 2013, provided they operate at a power level of less than 10 microwatts e.i.r.p., with a total duty cycle of 0.005% or less. In addition, the requirements of Section 5.7 do not apply to MEDS devices operating in 401.85-402 MHz that meet the exemption for the LBT criteria (see Section 3.6).

The requirements of Section 5.7 do not apply to MICS implants transmitting information as a result of a medical implant event (see definitions). In this case, the implant may immediately transmit time-critical data to an active medical implant peripheral without regard to channel occupancy (only permitted for (LBT/AFA, time critical data)). The length of a transmission as a result of a single medical implant event is limited to 30 seconds. The transmission of additional data beyond this time limit requires the establishment of a MICS communications session and the requirements for LBT/AFA shall be met.

5.7.1 System Threshold Power Levels

The monitoring threshold power level shall not be greater than the calculated level given by the equation $10 \log_{10}B$ (Hz) – 150 (dBm/Hz) + G(dBi), where B is the emission bandwidth of the MICS or MEDS 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. If the radio part of an active medical implant or a body-worn equipment outside the human body is used to select the frequency of operation for a MEDS system, the above LBT threshold level requirement may be adjusted higher 1 dB for every 1 dB the e.i.r.p. of the device performing the LBT and AFA function is below the maximum permitted level of -16 dBm e.i.r.p., provided no other device operating in the system has an e.i.r.p. greater than the device that selects the frequency of operation for the system. All MICS or MEDS programmer/controllers must have sufficient RF sensitivity to detect signals at a threshold level determined by the above equation, or by adjustment to the above equation in the case of MEDS devices operating below the maximum permitted e.i.r.p. level.

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 MICS monitoring system shall monitor all channels in the 402-405 MHz frequency band.

Within 5 seconds prior to initiating a communications session, circuitry associated with a MEDS monitoring system shall monitor all channels in the 401-402 MHz and 405-406 MHz frequency bands.

5.7.4 Minimum Channel Monitoring Period

Each MICS or MEDS 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 threshold. If no channel having an ambient power level below the threshold is available, the equipment under test shall access and transmit on the least interfered channel (LIC).

5.7.6 Discontinuation of a MICS or MEDS Session

MICS or MEDS transmitters 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 milliseconds 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 MEDS, 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 and MEDS 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 of all MITS devices shall be limited to 0.01% of an hour, and the number of transmissions shall not exceed 10 in any given hour.

The duty cycle of all MEDS devices operating in either the 401-402 MHz or 405-406 MHz bands that do not operate in a system that uses LBT for channel selection, and whose output power is at or below 250 nanowatts, shall be limited to 0.1%, and the maximum number of transmissions shall not exceed 100 in any given hour.

The duty cycle of all MEDS devices operating in the 401.85-402 MHz band that do not operate in a system that uses LBT for channel selection, and whose output power is at or below 25 microwatts, shall be limited to 0.1%, and the maximum number of transmissions shall not exceed 100 in any given hour.