

PCC.III/REC.51 (XIII-99)¹

**USE OF THE 401- 406 MHZ BAND BY MEDICAL IMPLANT
COMMUNICATION SYSTEMS**

The Thirteenth Meeting of the Permanent Consultative Committee III: Radiocommunications,

CONSIDERING:

- a) That the ITU has allocated worldwide the band 401-406 MHz to the Meteorological Aids, and portions of this band to Meteorological Satellite, Space Operations and Earth Exploration Satellite Services on a primary basis;
- b) That Recommendation ITU-R SA.1346, specifies the feasibility of sharing in the band 401-406 MHz between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) that are in compliance with the technical and operational characteristics described in the Recommendation;
- c) That interference mitigation techniques used by MICS equipment, as described in Annex 1 to Recommendation ITU-R SA.1346 provide a high level of protection to their operation from possible interference by the Meteorological Aids systems;
- d) That with a limit of -16 dBm on the e.i.r.p. of MICS equipment, MICS will not cause interference to the Meteorological Aids, Meteorological Satellite, Space Operations or Earth Exploration Satellite Services;
- e) That the World Meteorological Organization accepted the proposal for sharing of the band 401-406 MHz with MICS based on the interference analysis performed by the ITU;
- f) That, due to patient travel for personal and business reasons, MICS require a single band available worldwide, and may operate in the 401-406 MHz band on the basis that they do not cause interference to and that they accept interference from the Meteorological Aids, and other primary services;
- g) That spectrum occupancy studies have shown that a minimum of 3 MHz of spectrum in the 401-406 MHz band is needed to insure availability of at least one 300 kHz channel in some locations, and
- h) That the European Organization of Post and Telecommunications Authorities (CEPT) has adopted ANNEX 12 to CEPT/ERC/REC 70-03 to provide for 3 MHz of spectrum for MICS from 402-405 MHz,

RECOGNIZING:

- a) That MICS are designed for radiocommunication operation over a distance of 2 meters or less between an active implantable medical device that is implanted within a patient's body, and a separate programmer/controller used by a medical professional;

¹ Reference document: PCC.III/doc.1427/99

- b) That a radiocommunication link between a programmer/controller and a medical implant device occurs only occasionally;
- c) That implanted device proliferation is limited by medical need;
- d) That due to the ultra low power of MICS transmitters, no harmful interference would occur to the operation of Meteorological Aids, Meteorological Satellite, Space Operations and Earth Exploration Satellite Services from the MICS;
- e) That a channel bandwidth of up to 300 kHz will permit high data rate communication between devices operating in a MICS;
- f) That the applications for active medical implants serve a variety of purposes such as pacemakers, defibrillators, nerve stimulators, injection pumps, and others, and
- g) That among the many benefits to the public from this technology are improved patient quality of life and mobility, maintenance of a more sterile environment during implant surgery as a result of the extended communications distance and reduced medical costs resulting from more rapid diagnosis and treatment of the patient,

RECOMMENDS:

1. That the CITEL Member States consider adopting provisions, consistent with their national laws and regulations, to allow 3 MHz (402 - 405 MHz) of the 401-406 MHz band to be used by the MICS on the basis that MICS does not cause harmful interference to and can accept interference from the Meteorological Aids systems and other primary users.
2. That the e.i.r.p. of MICS transmitters be limited to -16 dBm (25 microwatts) in a reference bandwidth of 300 kHz in order to provide adequate protection from harmful interference to the Meteorological Aids systems and other primary users.
3. That the CITEL member states consider adopting a technical specification, as the one shown in the attached Annex, to ensure that the selection of the channel of operation is based upon the channel with the lowest ambient noise level.

ANNEX

TECHNICAL SPECIFICATION FOR A CHANNEL SELECTION AND SPECTRUM MONITORING PROTOCOL

A medical implant communications session must be initiated by a medical implant programmer/control transmitter. Medical Implant programmer/control transmitters must incorporate a system for monitoring the channel or channels that the MICS devices intend to occupy. The monitoring system bandwidth must be equal to or greater than the emission bandwidth of the MICS session transmitter with the greatest bandwidth. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before a medical implant programmer/control transmitter initiates a MICS communications session, the following spectrum access criteria must be met:

1. Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer/control transmitter must monitor the channel or channels the MICS devices intend to occupy for a minimum of 10 milliseconds per channel.
2. Based on use of an isotropic monitoring system antenna, the monitoring system measured power level must not be more than $10\log B(\text{Hertz}) - 150 (\text{dBm/Hertz}) + G (\text{dBi})$ where B is the emission bandwidth of the MICS communication session transmitter having the widest emission and G is the medical implant programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.
3. If no signal in a MICS channel above the calculated monitoring threshold power level is detected, the medical implant programmer/control transmitter may initiate a MICS communications session involving transmissions to and from a medical implant device on that channel. The MICS communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (3) above is unavailable, the channel with the lowest ambient power level may be accessed.
4. When a channel is selected prior to a MICS communications session, it is permissible to select an alternate channel for use if communications is interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:
 - (i) Before transmitting on the alternate channel, the channel must be monitored for a period of at least 10 milliseconds.
 - (ii) The detected power level during this 10 millisecond or longer period must be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

- (iii) If the alternate channel provision is not used by the MICS or the criteria in (i) and (ii) above are not met, a channel must be selected using the access criteria specified in paragraphs 1 through 4 above.

MICS communications sessions that are initiated by a medical implant event are not required to use the above access criteria.

As used above, the following definitions apply:

1. Emission bandwidth. Measured as the width of the signal between the points on either side of carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance will be determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth of the device under test.
2. MICS Channel. 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.
3. MICS communications session. A collection of transmissions that may or may not be continuous between MICS devices.
4. Medical implant event. An occurrence or the lack of an occurrence recognized by a medical implant device, or duly authorized health care professional, that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted.