DUPLICATE

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and	)	
95 of the Commission's Rules	)	
To Establish the Medical Implant	)	RM No. 9157
Communications Service in the	)	
402 - 405 MHz band	)	

To: The Commission

PETITION FOR RULE MAKING

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Summary

Medtronic, Inc., of Minneapolis, Minnesota, a world leader in the development of medical implant devices, urges the Commission to issue a notice of proposed rule making calling for the creation of the Medical Implant Communications Service (MICS) under Part 95 of the Rules in the 402 - 405 MHz band. MICS operations would provide for the transmission of data to and from implanted medical devices such as cardiac pacemakers and defibrillators via high speed (100 kbps or more) short-range ultra low power (25 microwatts) wireless links. MICS systems would replace the cumbersome slow speed inductive coupling technology now used.

MICS operations would increase patient comfort and safety while reducing the cost of medical treatment. Conservative estimates of the cost savings run into multiple millions of dollars per year. Patients would run lower risks of infection during the implantation of medical devices. Physicians would be able to obtain vast amounts of data useful for diagnostic and therapeutic purposes. MICS also would aid in the development of new telemedicine applications.

MICS would be licensed by rule without individual station licenses. It would operate on a secondary basis to stations in the Meteorological Aids ("Metaids") Services. The proposed operations have been examined in both U.S. and international forums and found to be compatible with Metaids operations, if conducted under the limitations proposed herein. Use of a portion of the 401.000- 406.000 MHz Metaids band for MICS would set the stage for similar compatible uses around the world because of the international secondary mobile allocation in the Metaids band within all three ITU Regions.

The following figures illustrate the operation of MICS systems and contrast that operation with the methods currently used to communicate with medical implant devices.

At Device Implant

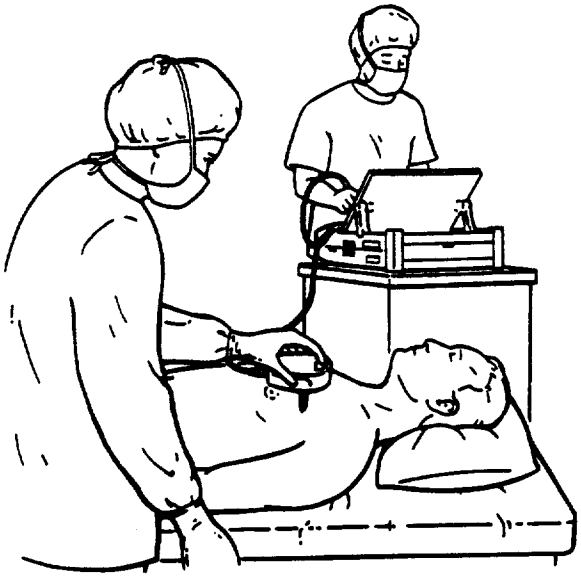

Figure 1A

With the current system: The physician must precisely place the programming head directly over the open incision into which the device has just been placed, which increases the risk of infection. During communication, the programming head must not move, making it necessary for the programmer operator to describe the display to the physician. If the patient moves, the communication link can be broken during the transmission of vital data. Finally, the cord between the patient and the programmer can literally be a stumbling block, limiting the mobility of medical personnel and equipment.

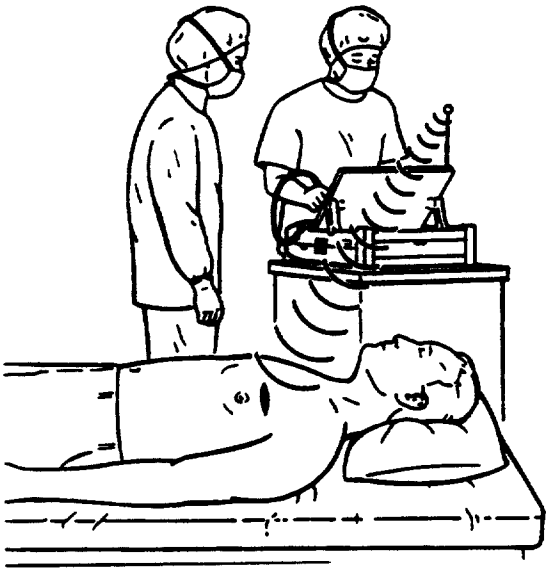

Figure 1B

With MICS: The physician can leave the sterile field and view the implanted device's information in real time. Eliminating the programming head reduces the risk of infection and the problems associated with the cord. Patient movement during the procedure has no impact on communication.

At Device Follow-up

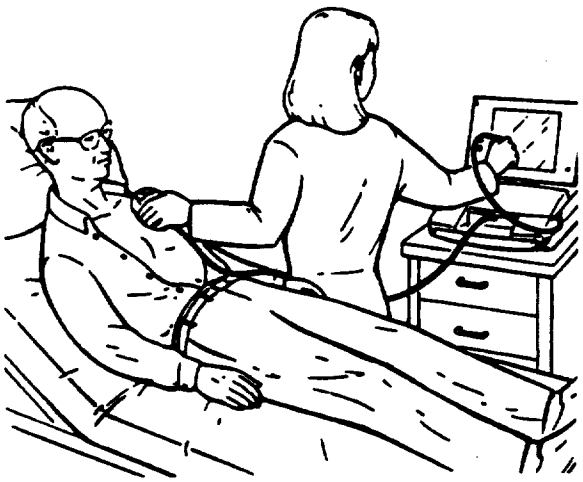

Figure 2A

With the current system: Patients return to their physician on a regular basis (typically the day after implant and then every 6 to 12 months) to have their device's performance evaluated. Establishing communication with the device often requires the patient to disrobe so the device can be found visually and tactually (a result of the current system's very small functional volume). This procedure can be painful, because the area of the incision may be quite tender. During communication, programming head position must be precisely maintained, precluding the physician from performing other duties.

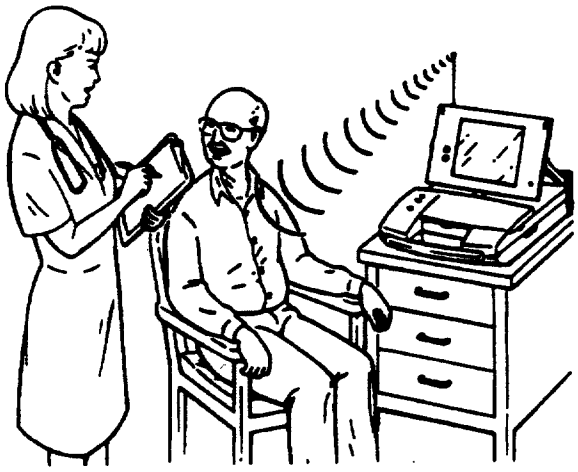

Figure 2B

With MICS: Communication occurs "hands-off," allowing the physician to work with the patient or perform other tasks during device interrogation. In cases where a significant amount of data needs to be recovered, the transaction can occur without medical personnel in attendance. Additionally, there is no need for the patients to disrobe or have their "personal space" violated.

In-Home Monitoring

Figure 3A

With the current system: The current system is too difficult for patients to operate, preventing the wide deployment of home monitoring. Patients are often intimidated by technology or forget to use the system. Additionally, the size and weight of the programming head make it very difficult for a patient to establish and maintain the link. The resulting data are often suspect, resulting in the need for additional transmissions and unnecessary office visits.

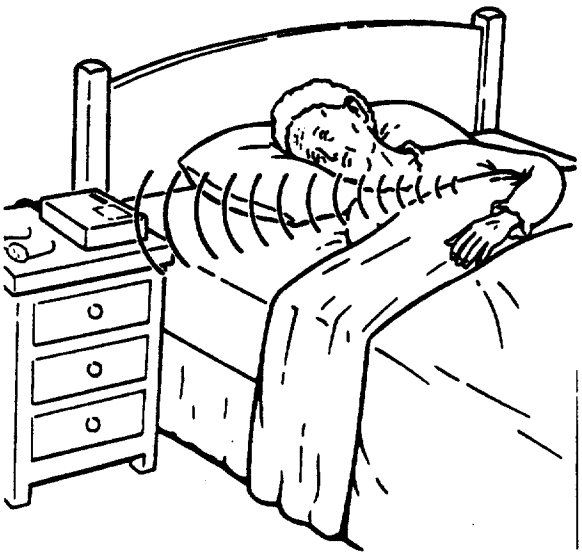

Figure 3B

With MICS: Home monitoring will become a convenient and inexpensive way to care for patients. With this capability, device and patient status can be monitored automatically by a bedside device and the data transmitted to the physician, which will shorten hospital stays as well as reduce clinic and hospital visits. Clearly this will reduce the cost of care and improve the patient's quality of life.

In-hospital Monitoring

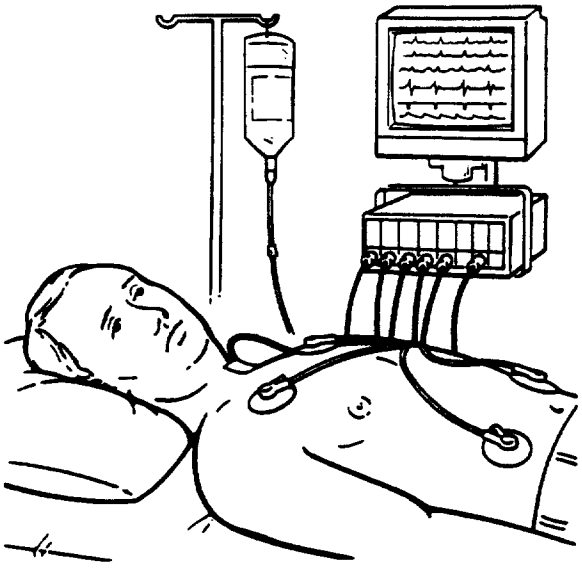

Figure 4A

With the current system: Patients with congestive heart failure and similar diseases frequently return to the cardiac care unit (CCU) as their disease progresses. In the CCU, patients repeatedly undergo dangerous and expensive catheterizations. These catheters measure physiological parameters, such as cardiac output, and are used in conjunction with surface electrodes. These electrodes cause contusions and infections.

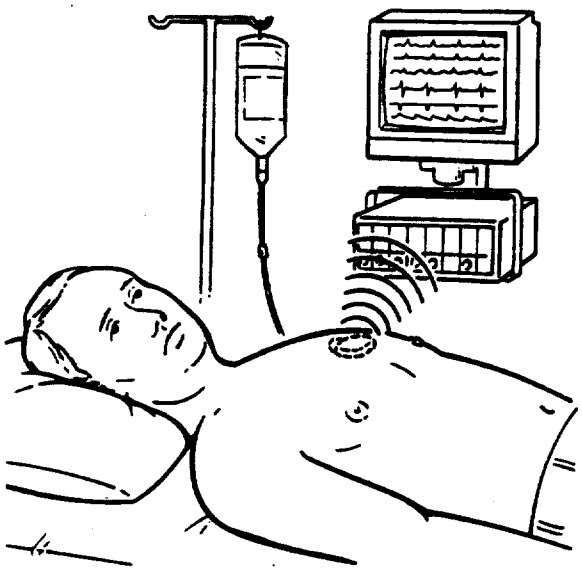

Figure 4B

With MICS: Implantable hemodynamic monitors measure physiologic parameters from within the body. These devices are inserted under the skin and the incision is closed, reducing the potential for complications. Physicians have real time access to parameters whenever the device is activated, which significantly reduces health care costs. In addition to using the devices in the hospital, the same devices can be used for home monitoring, which allows for better control of drug dosages, reducing re-admissions to the hospital. Wireless links to implantable monitors will provide a safer, cheaper, less invasive way to diagnose and manage patient condition.

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To: The Commission

PETITION FOR RULE MAKING

Medtronic, Inc., by its attorneys and pursuant to Section 1.401(a) of the Commission's Rules, hereby petitions the Commission to initiate a rule making to establish the Medical Implant Communications Service ("MICS") -- a private, ultra low power mobile radio service for transmitting non-voice data in support of the diagnostic and/or therapeutic functions associated with implanted medical devices.

Implanted medical devices serve the welfare of millions of people worldwide. The proposed radio service would greatly improve the utility of such devices and enhance the quality of life for patients by allowing physicians to establish high speed, easy-to-use, reliable, short-range, wireless links to interconnect implanted medical devices with monitoring equipment. The new generation of implantable medical devices developed under MICS would provide a safer, less expensive, and less invasive method to diagnose and manage patient conditions than the inductive systems now used.

For MICS technologies to be deployed successfully, 3 MHz of continuous bandwidth should be allocated in the United States and other countries. Based on a review of all relevant U.S. and international regulations, Medtronic has concluded that the only available spectrum that meets the MICS system design requirements is the 402 - 405 MHz portion of the Meteorological

Aids ("Metaids") band. As proposed, MICS would operate on a secondary, non-interference basis in this band.

Accordingly, Medtronic urges the Commission to (1) amend of the Table of Allocations at Section 2.106 of the Commission's Rules to allow the shared use of the 402 - 405 MHz band for MICS, on a secondary basis to the Meteorological Aids Service; and (2) modify Part 95 of the Commission's Rules to permit the operation of ultra low power MICS transmitters without an individual license. Proposed draft regulations are set forth in Appendix A.

I. BACKGROUND

Medtronic, established in 1949, is a world leader in medical implant technology. Headquartered in Minnesota, Medtronic conducts business in 120 countries and is the largest manufacturer of implantable medical devices. In the 1996 fiscal year, Medtronic devices served 1.4 million people worldwide. It manufactures medical implants that regulate heart rates (by means of pacing and/or defibrillation), control pain, improve motor functions, treat neurological tremors, administer medication, and control incontinence. For example, Medtronic produces about half the pacemakers in the world, including more than two million implanted since 1960. In the United States, approximately 400,000 persons currently depend on Medtronic pacemakers to regulate the rhythm of their hearts. Doctors implant Medtronic pacemakers in an additional 75,000 new patients each year.

Medical implants perform an expanding variety of diagnostic and therapeutic functions that benefit millions of people worldwide. Medtronic is constantly developing improvements in medical implant technology, and is currently developing new implantable medical devices to help an increasing number of patients with a wide range of medical problems, including atrial fibrillation, congestive heart failure, Parkinson's disease and cerebral palsy.

II. NEED FOR THE PROPOSED RULEMAKING

A. The Limitations of Current Medical Implant Devices

Medical implant devices allow physicians, among other things, to adjust the parameters of the device (*e.g.* pacing rate), receive information stored within the device (*e.g.* electrocardiograms), and monitor real-time transmissions of vital information for short periods (*e.g.* cardiac performance during the implant procedure).

Despite these significant benefits, there are two notable technical limitations with the available devices that prevent them from providing even greater benefits to patients: first, they use magnetically coupled coils in the implant and the programming head to establish a communications link and, second, they operate at 175 kHz. Thus, the current technology requires physicians to place a programming head directly on the skin of the patient as close as possible to the implanted device in order to establish a communications link with the device and to prevent any corruption or break in the link caused by the patient's movement. Moreover, the implants transfer data at an excessively slow rate of about two kilobits per second, requiring interrogation periods of up to 15 minutes. These periods are likely to increase to hours due to the expansion in data capacity expected in the near future. [1]

The adverse effect of these two limitations on patient care is substantial. For example, the current technology poses a number of problems during the surgery to implant the medical device. The physician must precisely position a programming head over the open incision into which the device has just been placed, which increases the risk of infection. See Fig. 1A *supra*. Any movement by the patient can break the communications link during the transmission of vital data, which delays the completion of the surgery. In addition, the cord linking the programming head to the associated reader limits the mobility of medical personnel and equipment. Last,

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[1] Today's devices can require in excess of 15 minutes to interrogate 256 kilobytes of stored electrocardiograms. If memory capacity continues to quadruple every three years as it has, interrogation periods will soon become unmanageably long.

physicians or attendants must constantly monitor the patient and equipment to ensure it is functioning properly.

The current technology also poses problems for patients. When patients return after surgery -- typically the day after implant -- for an evaluation of the performance of the device, they must disrobe so that the programming head may be placed directly over the location of the device. This can be painful because the area of the incision may be very tender. The patient must then lie motionless during the interrogation of the device to ensure that the communications link is not broken. See Fig. 2A. *supra*. Moreover, patients often must remain under such uncomfortable or even painful conditions for relatively long periods of time because of the slow data transfer rates associated with the current technology. These problems plague patients during the entire useful life of an implanted medical device, beginning from the moment the device is implanted and continuing through routine check-ups usually every three to twelve months.

These same limitations affect the utility of home monitoring of implanted devices. Weak or elderly patients often are unable to hold the heavy programming head over the implant area without moving for a sufficient period of time to establish and maintain a good communications link. See Fig 3A *supra*. For this reason, the data obtained from home monitoring are often unreliable.

In sum, the difficulty of establishing and maintaining an adequate communications link using currently available implanted medical devices has prevented patients from enjoying the full benefits that such devices have to offer. A communications system that would allow physicians or patients to establish and maintain a painless and sterile communications link would benefit the public interest and significantly lower health care costs.

B. The Medical Implant Communications Service ("MICS")

Medtronic is developing a wireless communications system for implanted medical devices that will dramatically improve the quality of life for patients, enhance the abilities of physicians, and lower health costs.[2] The two key attributes of this new system that enable this improvement are a minimum operating range of 2 meters and a 100 kbit/second (patient to programming device) data transmission rate.

MICS would resolve many of the limitations associated with the current technology identified above. See Fig. 1B *supra*. For example, a physician would be able to communicate with the device from outside the sterile field during implantation and view information from the device in real time, which reduces the risk of infection. Nor would the communications link likely to be lost so as to delay the surgery. Additionally, there is no cord required to connect a programming head and associated readers limiting the mobility of medical personnel.

After surgery, physicians could test the performance of the device without making the patient uncomfortable because a programming head would not be placed on the incision. See Fig. 2B *supra*. Patients would not need to disrobe nor have their privacy violated during interrogation. Moreover, patients could move freely without affecting the communications link. The physician could work with the patient or perform other tasks during device interrogation, such as measuring blood pressure, because communication would occur through a wireless link that would not require attention. The process could be completed quickly and comfortably even where a significant amount of data must be transmitted because of the higher data transmission rate. This higher data exchange rate also would allow communications to keep pace with the rapidly increasing storage capabilities of implanted medical devices.

Wireless links would be a more convenient and inexpensive way to care for patients at home as well. Patients would not need to hold a programming head to the device and remain

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[2] Although Medtronic filed this petition and describes the service it is developing, MICS would support medical implant communications systems from multiple manufacturers. As proposed, MICS is a non-exclusive service in which all equipment that meets certain basic technical standards designed to limit interference would have access to spectrum.

motionless. For example, a bedside device could automatically monitor the status of an implant and patient and transmit the data to the physician. See Fig. 3B *supra*. As a result, hospital stays as well as clinic and hospital visits would be minimized, thereby reducing the cost of health care and improving the quality of life for many patients.[3]

MICS also will improve the way certain in-hospital monitoring is performed. Patients with congestive heart failure and similar diseases frequently return to a cardiac care unit ("CCU") as their disease progresses. In the CCU, patients repeatedly undergo dangerous and expensive catheterizations. Catheters measure physiological parameters such as cardiac output and are used in conjunction with surface electrodes that cause contusions and infections. MICS would allow use of implantable hemodynamic monitors ("IHMs") that measure physiologic parameters from within the body. See Figs. 4a and 4b *supra*. IHMs are inserted under the skin and the incision is closed, which reduces the potential for complications. Physicians would have real time access to parameters whenever the device is activated, significantly reducing health care costs. In addition to using the devices in the hospital, the same devices could be used for home monitoring, allowing for improved care. For example, the devices could be used to control drug dosages, thereby reducing re-admissions to the hospital.

C. MICS System Requirements

In order to be successful, MICS should be allocated 3 MHz of continuous bandwidth within which to select at any given time the needed 300 kHz of "clean" (*i.e.* low noise) spectrum to establish a communications link with an implanted medical device. Moreover, implanted medical devices will often be in a patient for 10 or more years, making it imperative to operate

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[3] While a precise determination of the cost savings is difficult to calculate, two examples are useful. First, over $15M dollars per year would be saved by eliminating the need to conduct quarterly interrogation of implanted cardiac defibrillators in the clinical setting. This estimate does not include the interrogation of pacemakers, which are implanted at a much higher rate than defibrillators. Second, over $37B is currently spent annually on hospitalization due to heart failure. When devices currently under development for the management of heart failure incorporate the MICS technology, it is expected that there will be a meaningful reduction in hospitalization costs. Assuming this impact is as small as 5%, the savings would be nearly $2B per year.

in a well-controlled portion of the band to limit the potential for interference today and in the future. MICS also requires use of a band that is likely to be available in other countries throughout the world. International compatibility is needed to accommodate the mobility of patients and programmer units.

Given the amount of spectrum needed and the lack of spectrum available worldwide for allocation on a primary basis, the only option appears to be for MICS to operate in an existing allocation on a secondary, non-interference basis. Fortunately, the characteristics and application of MICS make it well suited to such operation. MICS requires a power of only -16 dBm (25 uW) EIRP to be effective and will be used largely indoors usually in urban areas, which virtually eliminates the potential for MICS to interfere with other services. The communication link of an implanted medical device is used only 0.0045% of the time, because the primary purpose is of the device is therapeutic, thereby further reducing the possibility of interference.[4] Nonetheless, MICS will need to manage allocated spectrum efficiently to avoid any possible interference from non-MICS sources and to support operations within clinics and hospitals where multiple systems may be engaged simultaneously.

D. Use of the 402 - 405 MHz Portion of the Spectrum

The technical and functional requirements of MICS -- relating to power consumption, size, receiver design, implant and programmer antenna performance, and bandwidth -- make the choice of spectrum critical to the success of MICS. After careful analyses of these requirements and international regulations and after consultation with the appropriate authorities, Medtronic has determined that use of the 402 - 405 MHz band appears to be the only viable spectrum

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[4] The same battery that powers the medical implant device would supply power for the communications. Communications must therefore be limited in order to maximize the life of the battery and its associated medical implant device. Given the current state of the art, the batteries in medical implant devices are not replaced; instead the devices are typically replaced in their entirety at the end of their battery life (*e.g.* 10 years).

option. Therefore, Medtronic proposes that MICS be designated as a secondary use of the 402 - 405 MHz part of the Metaids band.[5]

1. **Power Consumption** The communications circuitry of a medical implant device would be designed to consume less than 5 mW of power. Power consumption is a critical factor for medical implants. Implants have a limited power source that must be conserved and managed to last for the life of the patient or implant. The procedure for replacing an implanted medical device is both expensive and risky. Power consumed for wireless communications would reduce the power available to perform an implanted medical device's primary functions, which include gathering diagnostic data and delivering therapy to the patient. When transmitting, the implant transmitter must radiate enough power, at the expense of battery life, to overcome broadband natural and man-made interference, which decreases as frequency increases. Consequently, a trade-off between required transmit power and power consumption must be made; too much power sacrifices battery life, but too little power compromises the ability to overcome interfering noises. Thus, because power consumption increases with frequency, operation in any frequency band above 450 MHz would consume far more power than is acceptable.

2. **Size** As can be imagined, size is an important consideration for implanted medical devices. Larger devices cannot be used in children and often require the device to be implanted in locations more prone to complication. The size of the device can be conserved by using surface acoustic wave ("SAW") components for the implant receiver's preselector filter and integrated circuits for other filter functions. SAW devices perform well between a few hundred megahertz and a gigahertz and occupy less volume than the discrete filters required at lower frequencies. Consequently, size requirements can be met if the frequency of operation is in the 250 to 450 MHz frequency range.

3. **Receiver Design** The power consumption and size constraints make it difficult to design a receiver that handles interference well. The target power consumption of less than 5

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[5] Internationally, there is a secondary mobile allocation at 401.000 - 406.000 MHz in all three ITU regions.

mW limits the implant receiver's dynamic range. Relatively poor dynamic range eliminates the possibility of operating at frequencies near those allocated to high power transmitters such as broadcast television. In the United States, these constraints limit operation to between 216 MHz and 470 MHz. The presence of a host of land mobile systems around a typical hospital further limits the choice of spectrum because of potential interference from such systems that operate in the 450 - 470 MHz band at orders of magnitude more power than will MICS transmitters.

4. **Antenna Performance** Antenna performance of both the implanted device and the programmer also affects the decision as to what portion of spectrum may be used for MICS. The antenna performance for the implanted device is severely reduced by the conductivity of the body tissues and fluids. The reflection at the air-tissue boundary and plane wave attenuation in the media further increase the path loss. While losses due to body tissues and fluids increase with frequency, losses due to reflection decrease with frequency. Operation above several hundred MHz introduces more loss into the link than can be overcome by a device with such a low power budget, but operation at below 250 MHz introduces more reflection into the link than is acceptable.

The programmer antenna must have reasonable gain at lengths of 30 cm or less, because the programmer unit must be truly portable.[6/] Moreover, spatial diversity on the programmer unit is required to maintain a reasonable link margin. Research has shown that the antennas can be separated by no less than ¼ of a wavelength for spatial diversity to be of value in improving the quality of a wireless communications link. Thus, at 250 MHz, two antennas would need to be separated by a minimum of approximately 1 foot in order to benefit from spatial diversity. However, if antennas were separated by much more than 1 foot, the MICS programmer would be too large to be truly portable. Consequently, the lowest allowable frequency is about 250 MHz, with higher frequencies yielding better performance.

6/ This is the unit that would operate outside the human body and communicate with the MICS transmitter and receiver, which would be part of the medical device located inside the body.

5. **Bandwidth** The bandwidth requirements of MICS devices also limit spectrum choices. These requirements are determined by three factors: rate of data transmission, channelization, and preselector frequency accuracy. To support a 100 kbps uplink (implant to programmer unit) data rate using frequency shift keyed (FSK) modulation, the uplink bandwidth must be approximately 300 kHz.[7] Because MICS will be used worldwide and under many conditions, the system will have to avoid interference by frequency agility. By using a SAW preselector with a front end bandwidth of about 3 MHz, MICS will support some ten unique channels, depending on data rate and modulation technique. These channels are required to avoid the possibility of multiple programmer units interfering with each other and to allow the system to avoid the many 1 MHz wide interferers that have been measured in clinical environments.[8] Thus, channelization will help to protect patients from any jamming or data corruption occurring as a result of another device being within range.

E. The Limitations of Other Medical Communications Options

Although the FCC has made other spectrum available for use by physicians and health care providers in Part 15, technical considerations make this spectrum incompatible with MICS. Part 15 of the Commission's rules permits operation of biomedical telemetry devices in the 174-216 MHz band (VHF TV channels 7-13) with field strengths of 1500 microvolts-per-meter, measured at three meters,[9] and in the 512-566 MHz band (UHF TV channels 21-29) with field strengths of 200 microvolts-per-meter, measured at three meters.[10] As discussed above, both the

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[7] While narrower bandwidths are possible for conventional communications systems that transmit a 100 Kbps signal using more complex circuits, power consumptions and device size will require that about 300 kHz of bandwidth be employed in the uplink (implant-to-programmer receiver). However, since the downlink data rate will be lower and on the same frequency, the downlink bandwidth will be less than the uplink bandwidth.

[8] See Appendix B. Computers and other RF generating devices are routinely used in hospitals, which complicates the maintenance of electromagnetic compatibility at system levels because of the RF noise generated by these devices.

[9] *See* 47 C.F.R. § 15.241.

[10] *See* 47 C.F.R. § 15.209(g)(2).

174-216 MHz and the 512-566 MHz bands are outside the range of spectrum best suited to propagation of radio signals within the human body. Moreover, medical devices operating in either band must share that spectrum with high power adjacent broadcasting stations. Finally, neither band lends itself to international compatibility as does the 402-405 MHz band. In sum, neither the 174-216 MHz band under 47 C.F.R. § 15.241 both as written and as proposed to be modified,[11] nor the 512-566 MHz band under 47 C.F.R. § 15.209 (g)(2) is compatible with the technical requirements of MICS.

Likewise, technical considerations make operation of MICS under Part 90 impracticable. Part 90 of the Commission's rules permits operation of biomedical telemetry devices in the 450-470 MHz bands.[12] First, the 450-470 MHz band is outside the preferred range of spectrum for propagation of radio signals within the human body. Second, the 450-470 MHz band is populated by relatively high-powered emitters.[13] Finally, the 450-470 MHz band is subject to a power limit of 20 milliwatts,[14] which is some 29 dB higher than the proposed power limit of 25 microwatts for MICS. Consequently, Part 90 is not an alternative for MICS operations.

Moreover, operation at power levels that would be necessary to overcome interference from other medical devices under Parts 15 and 90 could result in harmful interference to both Metaids and other devices sharing the frequency. At the proposed 402-405 MHz band, operation

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11 *See* Amendment of Part 15 of the Commission's Rules to Permit Operation of Biomedical Telemetry Devices on VHF TV Channels 7-13 and on UHF TV Channels, Notice of Proposed Rulemaking, E.T. Docket No. 95-177, 61 Fed. Reg. 3367 (January 25, 1996). By this action, the Commission proposes to amend Part 15 of its rules to allow biomedical telemetry devices to operate on a non-interference basis on VHF channels 7-13 (174-216 MHz) and on all UHF channels (470-806 MHz) at transmitter power levels not to exceed 5 milliwatts. Moreover, the 5 mw power level would be 200 times greater than that proposed for MICS, thereby increasing the risk of interference.

12 *See* 47 C.F.R. §§ 90.27, 90.238 and 90.267. Hospitals or healthcare institutions that already hold Part 90 licenses may operate medical devices, without additional specific authorization, with output powers up to 20 milliwatts. *See* 47 C.F.R. §§ 90.267(a)(5) and 90.267(b)(8).

13 *See, e.g.*, 47 C.F.R. §§ 90.17-27, 53, 63-81, and 89-95.

14 47 C.F.R. § 90.267(a)(5).

at a maximum of 25 microwatts would allow successful implementation of MICS systems without causing excessive power losses to the implanted devices or interference to Metaids.

F. The Need for International Compatibility

Finally, the 402-405 MHz band appears to be the only spectrum that supports 3 MHz of bandwidth worldwide. Unlike other medical communications systems, MICS has a greater need for international compatibility that cannot be met by building different domestic and international versions. Internationally, some nations may be unable to allocate, even on a secondary basis, the entire 402-405 MHz band. However, the use of at least a portion of this band will mean that U.S. travelers abroad will have a high probability of successful MICS operation. Conversely, persons traveling to the U.S. will not have to forego use of potentially life-saving technology.

III. INTERFERENCE MANAGEMENT

A. MICS Susceptibility to Interference

Given the importance of the proper operation of implanted medical devices, it is vital that patients suffer no harmful effects from interference. Patient harm from interference can arise in three forms: implant battery depletion through responses to false alarms; unavailability of a communications link when needed; and data corruption by interference. The patient can be protected through a number of interference management strategies. Some examples are described below.

A false alarm conceivably could activate an implanted device's response sequence, which conceivably could deplete the device's power source. Although false alarms pose a danger to the battery life of an implanted device, a communications link to the device must be available on demand. In order to be available on demand without endangering device longevity, an implanted device can be designed to activate its transceiver and have the system go through a channel identification and acquisition algorithm only when it detects a strong magnetic field (> 14 Gauss). If a communications link is not successfully established, the transceiver would return to

dormancy to conserve battery energy. This method of establishing a communications link has an extremely low false alarm rate and has been used with the current 175 kHz inductive systems.

When availability on demand is not a requirement, *e.g.* in home monitoring, the system can be designed to determine if a communications link is desired by polling at long intervals (typically for less than a second every 30 to 120 minutes). The signal qualification and channel acquisition process conceivably could be prolonged by interference, which wastes battery energy. To avoid this, the microprocessor can program an increased polling interval until the interference subsides. For troubleshooting purposes, the device can also report the problem during the next successful transaction.

Interference -- including impulse, narrowband and broadband -- also reduces channel availability. MICS systems can be designed to deal with impulse interference by using digital data transmissions with automatic repeat request ("ARQ") and forward error correction ("FEC"). MICS systems can avoid narrowband interference by using frequency agility. Although the primary users of the Metaids band could cause narrowband interference to MICS, the potential for a radiosonde system to interfere with MICS is essentially zero because the typical radiosonde bandwidth is 300 kHz and the proposed MICS allocation is 3 MHz, meaning that at least 10 radiosondes, each on a different channel, would have to be within 1 km to jam a frequency agile MICS system. Similarly, wind profilers ("WP") and data collection platforms ("DCP") are not likely to interfere with MICS because they tend to be geographically remote to MICS locations and both the DCP's low duty cycle as well as the WP's antenna directivity work to the advantage of MICS.

Broadband interference poses the greatest challenge to MICS systems. Should a broadband interferer make the entire band appear to be unavailable, one strategy would be to operate MICS transmitters at reduced range. The signal power at the surface of the body is approximately 1000 times stronger than at 2 meters, providing the opportunity to improve the signal-to-noise ratio up to 30 dB by moving closer to the patient.

To ensure patient safety, all data sent to and received from an implanted device must be accurate. To ensure accuracy, MICS systems will use multiple error detection techniques. First, serial numbers and/or addresses will identify all links. Second, once established, cyclic redundancy codes ("CRC") will validate all transmitted data, which lowers the probability of incorrectly programming implant parameters to about two in a billion. Third, each operation will have a limited valid command set. Geographic separation, operation times and the small coincidence of co-channel operation will afford additional protection against inaccurate transmissions. Consequently, the probability of a primary user or another source causing a programming error will be almost zero.

B. Non-Interference to Metaids Systems

MICS transmitters pose virtually no threat of interference to any part of the extensive Metaids infrastructure, which is of great importance to the public. Current users of the Metaids band include radiosondes, rocketsondes, dropsondes, data collection platforms and wind profiling radar systems. Of these users, radiosondes appear to have the greatest susceptibility to interference, which is determined primarily by MICS transmitters' radiated power and the radiosonde's interference tolerance and secondarily by geographic proximity, MICS transmitter density, MICS transmitter duty cycle (including uplink and downlink ratios), and radiosonde duty cycle.

The International Telecommunications Union places the maximum permissible interference tolerance level for a radiosonde receiver at -161.5 dBW/300 kHz. The most conservative models predict that, even if both the radiosonde receiver and the MICS programmer/control transmitter were 2 meters above the surface of the earth, the MICS device would need to be within 300 meters to interfere with radiosonde operation.[15] For a radiosonde

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[15] Appendix C sets forth a compatibility analysis of MICS operation in a portion of the Metaids band. This analysis was developed and vetted in the U.S. and the ITU-R World Radio Conference preparation effort.

receiver height of 10 meters, a MICS device would need to be within 500 meters of the radiosonde receiver to interfere with Metaids operation. As the compatibility analysis demonstrates, MICS' very low transmit power greatly reduces the potential for interference. However, the probability of interference also is reduced by geographic orthogonality, [16] the density of MICS operating transmitters,[17/] MICS transmitter frequency agility, and MICS transmitter duty cycle.[18]

Consequently, the typical radii for a MICS device to interfere with a radiosonde will be much less than 500 meters. In the rare cases where a MICS device is within 500 meters of a radiosonde, the probability of interference is greatly reduced by the low MICS duty cycle, half duplex operation and the duty cycle of the radiosonde system.

IV. PROPOSED RULE CHANGES

Medtronic requests that the Commission issue a notice of proposed rule making proposing to (1) amend the Table of Allocations at Section 2.106 of the Commission's rules to accord the Medical Implant Communications Service a secondary allocation in the 402-403 and 403-405 MHz bands, and (2) revise Part 95 of the Commission's Rules to permit the operation of

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16 Radiosonde receivers tend to be located in rural areas while MICS applications are generally in population centers (hospitals and clinics). Communication in homes will occur much less frequently than in hospitals and clinics.

17/ Although there will be numerous medical implants located throughout the U.S., realistically, the only sites of potential interference are those in which transmitters are used extensively such as cardiac clinics where MICS communications will occur throughout the day. A given clinic may have multiple programmers, but the total number of such programmers will be orders of magnitude less than the number of implant transmitters. For example, Medtronic has about 15,000 programmer units worldwide using 175 kHz.

18 Since communication with an implanted medical device shortens its therapeutic or diagnostic lifetime because of battery drain, use of MICS will be kept to an absolute minimum. Individual implants have a communications duty cycle of about 0.0045% over their lifetime. Therefore, even if a particular implant were to interfere with Metaids, it would be unlikely for the interference to occur again.

ultra low power MICS transmitters in those bands without an individual license issued by the FCC.

The proposed rule changes are entirely consistent with past FCC actions and current policies with respect to medical devices that promise significant public interest benefits without a significant risk of interference to existing services. For example, the Commission has: (1) permitted the shared use of the 216-217 MHz band, on a secondary, non-interference basis, for the new Low Power Radio Service to include auditory assistance devices, health care assistance devices, and law enforcement tracking systems;[19] (2) exempted medical magnetic resonance systems from the Part 18 technical standards and authorization requirements;[20] (3) eliminated separate licensing requirements for low-power medical devices operating on a secondary basis in the 450-470 MHz band;[21] (4) exempted nonconsumer medical ultrasonic diagnostic and monitoring equipment from the technical standards and certain administrative requirements;[22] and (5) consistent with the mandates of the Telecommunications Act of 1996, facilitated the development of telemedicine.[23]

Medtronic urges the Commission to move forward to implement a regulatory program for MICS consisting of: (1) authorization by rule without license on the condition that harmful interference is not caused to stations in the Meteorological Aids Services and that MICS stations

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[19] Amendment of the Commission's Rules Concerning Low Power Radio and Automated Maritime Telecommunications System Operations in the 216-217 MHz Band, WT Docket No. 95-56 (rel. Aug. 2, 1996).

[20] In the Matter of Amendment of Part 18 To Remove Unnecessary Regulations Regarding Magnetic Resonance Systems, 9 F.C.C. Rcd. 3389 (1994).

[21] *See* Licensing of Low-Power Medical Devices in the 450-470 MHz Band, 7 F.C.C. Rcd. 5464 (1992).

[22] Amendment of Part 18 of the FCC Rules to Exempt Medical Ultrasonic Diagnostic and Monitoring Equipment from Technical Standards, 1 F.C.C. Rcd. 553 (1986).

[23] Federal-State Joint Board on Universal Service, CC Docket No. 96-45, Report and Order, released May 8, 1997, at ¶¶ 608-738 (discussing FCC efforts to support health care providers).

accept interference from stations in the Meteorological Aids Services; and (2) approval of MICS transmitters under the Commission's equipment authorization program.

To ensure that neither Metaids nor MICS experiences any interference, the Commission should also adopt specific technical standards. In particular, the Commission should prescribe: (1) operation in the 402-405 MHz band; (2) a maximum authorized bandwidth of 300 kHz; (3) a prohibition of voice transmission; (4) a limit on emissions more than 250 kHz outside of the MICS band (402-405 MHz) to specified levels no greater than the field strength limits now set forth in Section 15.209 of the Rules; (5) a maximum power limit of 25 microwatts EIRP; and (6) a maximum field strength from a MICS transmitter of 9.1 mV/m at 3 meters as measured with an instrument having a peak detector function.[24] Appendix A, attached hereto, proposes specific language for the rule changes required in Parts 2 and 95.

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[24] The field strength of the signal from the medical implant transmitters would be measured with the transmitter and its antenna placed in a medium designed to simulate human tissue. Measurements of this kind are commonly made in evaluating medical implants for electromagnetic compatibility.

V. CONCLUSION

For the foregoing reasons, Medtronic respectfully requests that the Commission issue a notice of proposed rulemaking to (1) amend the Table of Allocations at Section 2.106 of the Commission's Rules to accord MICS a secondary allocation in the 402-403 and 403-405 MHz bands, and (2) revise Part 95 of the Commission's Rules to permit the operation of ultra low power MICS transmitters in those bands without an individual license issued by the FCC. The proposed rules would allow greater use of life-saving medical technology without harming other users of the applicable frequency ranges.

Respectfully submitted,

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