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Washington, D.C. 20554**

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Federal Communications Commission
Office of the Secretary

In the Matter of)
)
Amendment of Parts 2 and 95 of the Commission's)
Rules to Establish the Medical Micropower)
Network Service in the 413-457 MHz Band)

RM-_____

RM-11404

PETITION FOR RULEMAKING

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TABLE OF CONTENTS

	Page
SUMMARY.....	ii
I. INTRODUCTION.....	1
II. BACKGROUND.....	2
III. THE PUBLIC INTEREST WOULD BE SERVED BY THE INTRODUCTION OF WIDEBAND MICROSTIMULATORS THAT CAN IMPROVE DRAMATICALLY THE QUALITY OF LIFE FOR MILLIONS OF PEOPLE WITH NEUROMUSCULAR DISORDERS.....	7
IV. THE COMMISSION SHOULD ALLOCATE SUFFICIENT SPECTRUM ON A SECONDARY BASIS TO ACCOMMODATE NEW WIDEBAND MMNS DEVICES.....	11
A. Currently Available Spectrum Cannot Support Wideband MMNS Devices.....	11
B. New Wideband MMNS Devices Require Four 5 MHz-Wide Channels.....	12
C. Spectrum Within The 413-457 MHz Band Is Ideally Suited To Support New Wideband MMNS Devices.....	14
V. THE COMMISSION SHOULD ADOPT SERVICE RULES TO ACCOMMODATE THE TECHNICAL REQUIREMENTS FOR WIDEBAND MMNS DEVICES.....	16
VI. THE PROPOSED OPERATION OF WIDEBAND MMNS DEVICES WILL MITIGATE THE RISK OF HARMFUL INTERFERENCE AND PROTECT PATIENT SAFETY.....	17
A. Mitigation Of Harmful Interference To Other Authorized Systems.....	18
B. Mitigation Of Harmful Interference From Other Authorized Systems ...	20
VIII. CONCLUSION.....	21
Appendix A: Proposed Rules for the Medical Micropower Network Service	
Appendix B: Medical Micropower Network Service System	
Appendix C: Engineering Statement of Jeffrey Binckes	

SUMMARY

The Alfred Mann Foundation for Scientific Research (“AMF”) urges the Commission to establish a new wideband medical micropower network service (“MMNS”) in the 413-457 MHz band. New spectrum allocation and service rules for MMNS will facilitate the development and deployment of revolutionary wideband medical implant devices designed to restore sensation, mobility, and other functions to paralyzed limbs and organs.

Each year, millions of Americans, including injured U.S. soldiers returning from the war in Iraq and other military operations abroad, suffer from spinal cord injuries, traumatic brain injuries, strokes, and various neuromusculoskeletal disorders. For these people, MMNS devices can serve as an artificial nervous system that replaces or improves the function of an impaired nervous system, thus providing invaluable therapeutic benefits and dramatically improved quality of life. These devices offer a safer, less invasive, and more effective treatment option than is available with existing, commercially available equipment. Without adequate spectrum and appropriate service rules, however, millions of Americans will be deprived of a safe and effective medical treatment for their debilitating health conditions.

Wideband MMNS devices require at least four 5 MHz-wide channels. In view of the lack of available licensed or unlicensed spectrum and the unique technical requirements of wideband MMNS devices, AMF has identified the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands as ideally suited to support MMNS operation on a secondary basis.

Accordingly, the Commission should (1) amend the Table of Allocations in Section 2.106 of the Commission’s rules to allocate 20 MHz of spectrum in the 413-457 MHz band for MMNS

on a secondary basis; and (2) revise Part 95 of the Commission's rules to authorize operation of MMNS devices without an individual license.

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PETITION FOR RULEMAKING

I. INTRODUCTION

The Alfred Mann Foundation for Scientific Research ("AMF"), pursuant to Section 1.401 of the Commission's rules, petitions the Commission to initiate a rulemaking proceeding to allocate sufficient spectrum and adopt service rules to permit a new wideband medical micropower network service ("MMNS") to operate on a secondary basis in the 413-457 MHz band.

New spectrum allocation and service rules for MMNS will facilitate the development and deployment of revolutionary wideband medical implant devices designed to perform functional electric stimulation and sensing ("FESS"), a technique that uses electric currents to activate and monitor nerves and muscles to restore sensation, mobility, and other functions to paralyzed limbs and organs. These devices can serve as an artificial nervous system that improves or replaces the function of an impaired nervous system, thus offering invaluable therapeutic, functional, and other benefits, including dramatically improved quality of life, for millions of Americans. Significantly, these devices can provide a critical component of the medical care given to the millions of disabled American veterans suffering from traumatic brain injuries, spinal cord injuries, or various neuromuscular disorders.

Existing Commission rules, however, do not permit operation of wideband MMNS devices designed to perform complex biomedical functions. Because these devices transmit substantial amounts of information in extremely short bursts, they require channel bandwidth of approximately 5 MHz. The unique attenuation properties of the human body makes the 400 MHz band ideally suited to support the successful deployment of this breakthrough technology. Based upon the relative existing use of the 400 MHz band, AMF has concluded that the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands are the preferred channels for MMNS devices.

For the last two and a half years, AMF has been testing and developing MMNS equipment under an FCC experimental license. AMF continues to make significant progress on the development of its MMNS equipment and urges the Commission to adopt allocation and service rules to facilitate the long-term development and deployment of this revolutionary technology.

Accordingly, AMF requests that the Commission (1) amend the Table of Allocations in Section 2.106 of the Commission's rules to allocate 20 MHz of spectrum in the 413-457 MHz band for MMNS on a secondary basis; and (2) revise Part 95 of the Commission's rules to authorize operation of MMNS devices without an individual license. AMF's proposed rule revisions are set forth in Appendix A.

II. BACKGROUND

Since 1985, AMF has served as a nonprofit research medical foundation dedicated to the exploration and development of advanced medical technologies that offer hope for significant improvements to the health, security, and quality of life for people suffering from debilitating medical conditions. AMF's mandate is to develop medical products that for-profit corporations

might not find economically feasible. All proceeds directly benefit the continued medical and scientific research of AMF.

AMF and its world-renowned scientists have a strong record of bringing innovative technical solutions to improve dramatically the lives of persons suffering from debilitating medical impairments. AMF conducted pioneering development work on a long-term, fully implantable glucose sensor for continuous monitoring of blood sugar levels in diabetics. This sensor, used in conjunction with an insulin delivery pump, can achieve a completely automated delivery process of insulin tailored to a patient's blood sugar level. This device eventually could replace a non-functioning pancreas for many diabetics.

AMF also undertook the development of an implantable high-speed cochlear implant with two-way telemetry to restore hearing to deaf patients. The AMF cochlear implant enables these patients to interpret speech and music. Today, thousands of patients are able to listen to and understand speech and music as a result of this breakthrough technology.

For the last several years, AMF has been developing wideband MMNS equipment designed to function as an artificial nervous system that performs FESS to activate and monitor nerves and muscles in order to restore sensation, mobility, and other functions to paralyzed limbs and organs. Examples of FESS applications include allowing paraplegics to stand, restoring hand grasp function for quadriplegics, and restoring bowel and bladder function. Although the main applications of FESS consist of restoring limb mobility and regulating organ function (in order to alleviate the effects of stroke, spinal cord injury, multiple sclerosis, traumatic brain injury, and other medical conditions and injuries), FESS also can be used for treatment of numerous debilitating medical conditions that are not responsive to pharmaceutical treatment, such as arthritis, pain, and migraine headache.

To test and develop its MMNS equipment, AMF, on January 6, 2005, obtained a five-year experimental license to operate the equipment in the 400-470 MHz bands. AMF's MMNS system consists of a wireless network of implantable microstimulators that produce electrical pulses to elicit muscle contractions and neural responses. As illustrated in Appendix B, the components of this system include (1) an external master control unit ("MCU") that coordinates the activities of all other system components;¹ (2) separate miniature, battery-powered, implantable microstimulators capable of sensing bodily signals or generating stimulation pulses; and (3) a recharging subsystem consisting of an external charger and coil assemblies.²

AMF, in partnership with Dr. Jane Burridge at the University of Southampton in the United Kingdom, already has commenced the first clinical trial involving an experimental version of the MMNS system, aimed at restoring arm and hand function for people who have been paralyzed after suffering a stroke.³ This study has resulted in significant recovery of

¹ The MCU is a portable device that may be carried by the patient or placed in a convenient location within a few meters of the patient. It is the communication and control hub that transmits and receives signals to and from all implanted devices in the system. Specifically, it coordinates the activity of the implanted devices by receiving sensing data from the implanted devices, processing that data, and creating a stimulation pattern in the appropriate implant devices by transmitting instructions based on the processed data to the implanted devices. It also serves as the basic user interface for the patient, providing system activation, alarms, program selection, and limited parameter control.

² The charger generates a magnetic field at 127 kHz with the external coil worn only when recharging the batteries in the implanted devices. The external coil includes a faraday shield to limit emissions levels in compliance with the FCC emission limits for unlicensed Part 15 devices. The MCU communicates with each implant device to determine which device requires recharging and when a device is fully charged. The recharging subsystem includes a temperature sensor that halts the recharging process if the external coil temperature were to rise above a predetermined level.

³ The experimental version of the MMNS system relies upon magnetic coupling, rather than an implantable battery, to supply power to the microstimulators.

function among the subject patients.⁴ In fact, after three months of stimulation, the first three subject patients experienced an improvement in their arm function by 44 percent, with a 60 percent reduction in spasticity of the wrist.⁵ AMF anticipates that the introduction of the next-generation of battery-powered MMNS devices will yield even better results and health benefits for patients.

AMF expects to complete construction of the first 200 fully functioning, battery-powered MMNS microstimulators by July 2008. AMF successfully has tested prototypes of the MCU and implanted microstimulators in animals, thus commencing *in vitro* and *in vivo* testing to verify system biocompatibility and operation. Upon successful completion of the required testing, AMF expects to introduce fully functioning MMNS devices in clinical studies involving human patients under the auspices of and pursuant to the rules and regulations administered by the Food and Drug Administration (“FDA”). Continued access to sufficient spectrum resources and Commission adoption of appropriate service rules, however, are critical to the long-term development and deployment of AMF’s MMNS equipment.

In response to the *MedRadio NPRM/NOI*,⁶ AMF submitted comments on October 31, 2006, urging the Commission to initiate a rulemaking to adopt spectrum allocation and service rules for new wideband MMNS devices. Nearly a hundred parties, representing various interests including private industry, the private and public medical establishment, and individual members

⁴ See Letter from Dr. Jane Burridge, Senior Lecturer and Principal Investigator, University of Southampton, to Kevin J. Martin, Chairman, FCC, at 1, ET Docket No. 06-135, RM-11271 (Nov. 20, 2006).

⁵ Dr. Burridge has been invited as a guest speaker at the International Stroke Conference in New Orleans, Louisiana, in February 2008, to discuss the results of the clinical trial.

⁶ See *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, 21 FCC Rcd 8164 (2006) (“*MedRadio NPRM/NOI*”).

of the U.S. military, filed responses expressing strong support for the proposed rulemaking. For example, the Director of the U.S. Department of Health and Human Services Office on Disability stated that MMNS devices “present a never before seen opportunity for persons with partial paralysis resulting from strokes, spinal cord injuries, neuromusculoskeletal disorders, and many other impairments to lead independent lives.”⁷ A representative of the U.S. Department of the Army at the Walter Reed Army Medical Center also noted that AMF’s MMNS devices “offer a safer, less invasive, and more effective treatment option than is currently available with existing equipment.”⁸ Similarly, a representative of the U.S. Department of Veterans Affairs stated that “[t]he wireless wideband ... microstimulator equipment that AMF is developing represents a major advance in [FESS] technology and in the rehabilitation of people living with paralysis due to stroke or spinal cord injury.”⁹ Additionally, the United Cerebral Palsy Research and Educational Foundation noted that “[w]ithout adequate spectrum and service rules to support the operation of these innovative [MMNS] devices, millions of Americans will be deprived of a safe and effective medical treatment for their debilitating health conditions.”¹⁰ All of these commenters are unanimous in calling for prompt Commission adoption of allocation and service rules to expedite deployment of MMNS technology.

⁷ See Letter from Margaret Giannini, MD, Director, Office on Disability, U.S. Department of Health and Human Services, Kevin J. Martin, Chairman, FCC, at 1, ET Docket No. 06-135, RM-11271 (Dec. 1, 2006).

⁸ See Letter from Paul F. Pasquina, M.D., Lieutenant Colonel, Chief of Physical Medicine and Rehabilitation Medical Director, U.S. Army, Walter Reed Army Medical Center, to Kevin J. Martin, Chairman, FCC, at 1, ET Docket No. 06-135, RM-11271 (Nov. 27, 2006).

⁹ See Letter from Robert L. Ruff, M.D., Ph.D., Acting Director of Rehabilitation Research, Veterans Health Administration, Department of Veterans Affairs, to Kevin J. Martin, Chairman, FCC, at 1, ET Docket No. 06-135, RM-11271 (Nov. 20, 2006).

¹⁰ See Letter from Mindy Aisen, M.D., Medical Director and CEO, United Cerebral Palsy Research and Educational Foundation, to Kevin J. Martin, Chairman, FCC, at 2, ET Docket No. 06-135, RM-11271 (Nov. 16, 2006).

III. THE PUBLIC INTEREST WOULD BE SERVED BY THE INTRODUCTION OF WIDEBAND MICROSTIMULATORS THAT CAN IMPROVE DRAMATICALLY THE QUALITY OF LIFE FOR MILLIONS OF PEOPLE WITH NEUROMUSCULAR DISORDERS

Each year, millions of Americans suffer from spinal cord injuries, traumatic brain injuries, strokes, and neuromusculoskeletal disorders such as cerebral palsy, osteoporosis, disuse atrophy, spasticity, cardiopulmonary dysfunction, epileptic seizures, muscle and joint contractures, arthritis, facial paralysis, debilitating migraine headache, urinary incontinence, and loss of muscle endurance and metabolic function. For example, approximately 700,000 Americans suffer from strokes each year. Americans were predicted to pay approximately \$62.7 billion in 2007 for stroke-related medical costs.¹¹

Approximately 250,000 to 400,000 Americans suffer from spinal cord injuries. Each year, approximately 11,000 U.S. residents sustain new spinal cord injuries.¹² Spinal cord injury and its associated lower limb paralysis leads to neuromusculoskeletal disorders such as osteoporosis, disuse atrophy, spasticity, and loss of muscle endurance and metabolic function. Those suffering from spinal cord injuries are at an increased risk for secondary diseases such as obesity, insulin resistance, hyperglycemia, diabetes, and cardiovascular disease. Additionally, depending upon the level of injury and age at the time of injury, the estimated lifetime costs that are directly attributable to a spinal cord injury can be as much as \$2.9 million (in 2006 dollars).¹³

¹¹ See American Stroke Association, Impact of Stroke, <http://www.strokeassociation.org/presenter.jhtml?identifier=1033> (last visited Jul. 26, 2007).

¹² See About Spinal Cord Injury, <http://www.spinalcord.org/html/injury.php> (last visited Jul. 26, 2007).

¹³ This estimate does not include indirect costs such as losses in wages, fringe benefits, and productivity. See Spinal Cord Injury: Facts and Figures at a Glance, <http://images.main.uab.edu/spinalcord/pdf/Files/Facts06.pdf> (last visited Aug. 7, 2007).

Additionally, approximately 764,000 children and adults in the United States manifest one or more of the symptoms of cerebral palsy. Each year, approximately 8,000 infants and 1,200 to 1,500 preschool children are diagnosed with the condition.¹⁴ According to the Centers for Disease Control and Prevention (“CDC”), the estimated average lifetime costs for a person with cerebral palsy is \$921,000 (in 2003 dollars).¹⁵ This represents costs over and above those experienced by a person who does not have a disability.

According to a 1999 CDC report, each year an estimated 1.5 million Americans sustain a traumatic brain injury, 80,000 to 90,000 of whom are expected to experience long-term disability as a result.¹⁶ An estimated 5.3 million Americans are living with a permanent disability resulting from a traumatic brain injury.¹⁷ One study estimated that the annual economic costs of traumatic brain injuries in the United States is \$37.8 billion (in 1985 dollars), including medical care expenses, injury-related work loss and disability, and lost income from premature death.¹⁸

Furthermore, osteoporosis is a major public health risk for an estimated 44 million Americans, or 55 percent of those who are 50 years of age and older. Approximately 10 million Americans suffer from the disease, and nearly 34 million more are estimated to have low bone mass, placing them at an increased risk for osteoporosis. The estimated national direct care

¹⁴ See United Cerebral Palsy Facts & Figures, http://www.ucp.org/ucp_generaldoc.cfm/1/9/37/37-37/447 (last visited Jul. 26, 2007).

¹⁵ See Centers for Disease Control and Prevention, *Economic Costs Associated with Mental Retardation, Cerebral Palsy, Hearing Loss, and Vision Impairment—United States, 2003*, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5303a4.htm> (last visited Aug. 7, 2007).

¹⁶ See Centers for Disease Control and Prevention, *Traumatic Brain Injury in the United States: A Report to Congress*, at 1, 1999, http://www.cdc.gov/ncipc/tbi/tbi_congress/TBI_in_the_US.pdf (last visited Aug. 7, 2007).

¹⁷ *Id.*

¹⁸ *Id.*

expenditures, including hospital, nursing home, and outpatient service costs, for osteoporotic fractures total approximately \$18 billion per year in 2002 dollars.¹⁹

The cases of traumatic brain injuries, spinal cord injuries, and various neuromusculoskeletal disorders continue to mount as injured U.S. soldiers return from the war in Iraq and other military operations abroad. For example, physicians with the Defense and Veterans Brain Injury Center at the Walter Reed Army Medical Center estimate that two-thirds of the U.S. casualties in Iraq have suffered brain injuries.²⁰

If successfully implemented, new pioneering wireless FESS devices could be used to treat these brain and spinal cord injuries, as well as the various neuromusculoskeletal disorders, more effectively and efficiently than with existing, commercially available FESS devices. These new devices also can be used to treat other maladies such as arthritis, headaches, and pain. Additionally, these devices can be used in conjunction with next-generation prosthetic limbs to provide wireless sensation and control to the prostheses, and significantly reduce the weight of the prostheses by replacing outdated, heavier systems. Thus, new wireless FESS devices offer nothing short of a revolutionary technology that could fundamentally improve the quality of life for millions of seriously disabled people, as well as significantly alleviate the impact of skyrocketing medical costs.

Although FESS has been implemented successfully in devices such as the cardiac pacemakers to pace the heart and cochlear implants to restore hearing, it has not been widely adopted as a means of rehabilitating paralyzed limbs and organs. The technology's potential to

¹⁹ See National Osteoporosis Foundation Fast Facts, <http://www.nof.org/osteoporosis/diseasefacts.htm> (last visited Jul. 26, 2007).

²⁰ See Spc. Chuck Wagner, *Brain injuries high among Iraq casualties*, Army News Service, Nov. 24, 2003, http://www4.army.mil/ocpa/read.php?story_id_key=5445 (last visited Aug. 7, 2007).

produce health benefits in these areas has been largely unfulfilled because of the limitations of commercially available equipment, which utilizes cumbersome wire electrodes that must be placed on the skin or partially or fully implanted underneath the skin.

The risks of commercially available systems are undeniable—hours of invasive surgery to implant devices connected through wires that, in many cases, are placed partly or entirely within the body. If an infection occurs, it is difficult to contain the infection and prevent it from spreading across the wires. In those cases, the net result is that the patient must undergo hours of additional surgery to remove the system.

AMF's MMNS system employs groundbreaking technology that can overcome the limitations of existing, commercially available equipment. Specifically, the miniature, battery-powered microstimulators are fully implantable by injection or other minor surgical procedure, and create within the body a wireless network capable of both delivering electrical stimulation and acting as sensors of various in-body attributes and functions. Depending upon the nature and extent of the neurological damage, approximately one to 100 microstimulators are envisioned for any given patient, although an average of two to 12 microstimulators is estimated for the typical patient. Each of these microstimulators is a cylinder that is approximately 3.4 mm. in diameter and 25 mm. long. With practice, each injection should require only a fraction of the time required to implant existing, commercially available wired systems. The small size and lack of wires implanted in the body render the microstimulators minimally invasive, thus typically avoiding the need for major surgery and its associated costs.

The lack of wires implanted in the body also means that there are no wires to break and that the implanted devices are less susceptible to infection. If an implanted device becomes

infected, the infection likely would not spread to other implanted devices because there are no wires along which the infection can spread.

Furthermore, the battery power feature of the implantable microstimulators eliminates the need for patients to wear an external, magnetically coupled coil during use to transmit power and data to the implanted device, thereby improving acceptance of the technology by patients, enhancing the reliability of the system, and enabling the mobility of patients uninhibited by cumbersome external wires and coils. Finally, the lack of an external coil is particularly beneficial for disabled people who are unable to put on and take off an external coil without assistance, ultimately reduce the cost of patient assistance.

IV. THE COMMISSION SHOULD ALLOCATE SUFFICIENT SPECTRUM ON A SECONDARY BASIS TO ACCOMMODATE NEW WIDEBAND MMNS DEVICES

A. Currently Available Spectrum Cannot Support Wideband MMNS Devices

No suitable spectrum is now available to accommodate wideband MMNS equipment. The spectrum generally available for wireless medical devices on a licensed basis primarily consists of (1) 14 MHz of spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands for wireless medical telemetry service (“WMTS”) under Part 95; (2) 3 MHz of spectrum in the 402-405 MHz band for medical implant communications service (“MICS”) under Part 95; and (3) frequencies in the 450-470 MHz band for low-power biomedical telemetry operations under Part 90 of the Commission’s rules.

WMTS spectrum is unsuitable for wideband MMNS devices because, as the Commission has found, frequencies above 470 MHz are outside the preferred range of spectrum for

propagation of radiofrequency (“RF”) signals within the human body.²¹ Moreover, WMTS and Part 90 spectrum above 450 MHz is congested and populated with commercial, high-power transmitters that could preclude reliable operation of lower-power, wireless medical implant devices. Additionally, although the Commission has proposed to expand the existing MICS band into a medical radiocommunications service band at 401-406 MHz, this spectrum is insufficient to accommodate new wireless medical implant devices that require much larger bandwidths and higher power levels to support much more complex functions.²²

B. New Wideband MMNS Devices Require Four 5 MHz-Wide Channels

Wideband MMNS devices require nearly 5 MHz of channel bandwidth for the following purposes: (1) to transmit large amounts of data necessary to perform complex biomedical functions; (2) to transmit heavily coded messages necessary to permit detection and correction of errors; and (3) to conserve battery power while minimizing the size of the battery and thus the size of the implantable microstimulator. First, unlike many commercially available implant devices that can operate with modest signaling rates requiring narrow channel bandwidths, wideband MMNS devices must use high, instantaneous data rates to provide therapeutic benefits

²¹ Specifically, the Commission found that the 174-216 MHz and the 470-668 MHz bands are “outside the range of spectrum generally considered to be the most suitable for propagation of radio signals within the human body. *See Amendment of Parts 2 and 95 of the Commission’s Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band*, 14 FCC Rcd 21040, ¶ 6 (1999).

²² Although Parts 15 and 18 of the Commission’s rules permit wireless medical devices to operate using various frequencies on an unlicensed basis, the technical restrictions under those rules prevent deployment of higher-power, wideband MMNS devices. Specifically, the emission limits under Sections 15.209(a) and 18.305(b) of the Commission’s rules are too stringent for wideband MMNS systems, which require higher power levels. Additionally, although Section 18.305(a) permits industrial, scientific, and medical equipment to operate at unlimited emission levels on certain frequencies, these frequencies are located below 41 MHz and above 900 MHz, which the Commission previously found to be outside the preferred range of spectrum for RF signal propagation within the human body. *Id.*

far beyond those of existing devices. The need for real-time data for motion control, auditory or visual prostheses, and other neural signaling functions requires substantially greater bandwidth than is available under the Commission's existing rules.

Second, in order to provide a robust communications link and protect against RF interference, MMNS devices employ a redundant coding technique that permits detection and correction of data transmission errors. This coding technique requires double the amount of bandwidth that otherwise would be required.

Third, size is a significant factor in the design of the microstimulators. These devices must be as small as possible to ensure that they can be easily injected and properly placed at precise locations, to maximize patient comfort, and to minimize the risk of infection or other complications. Consequently, the use of miniature batteries in the design of the microstimulators is critical. The extremely small size and limited capacity of the miniature batteries, however, impose severe constraints on battery power drain. The only mechanism for reducing power drain on the miniature batteries is to transmit and receive large amounts of data in very short bursts. Under normal operations, battery-powered microstimulators can operate without recharging for at least a day or more. These technical considerations require the microstimulators to use nearly 5 MHz of channel bandwidth.

Because AMF proposes to operate MMNS equipment on a secondary, non-harmful interference basis, access to at least four channels will be required to ensure that at least one channel will be available and to avoid harmful interference in the event that the other three channels are congested. MMNS equipment also will require access to at least four channels to ensure that multiple MMNS systems can be accommodated within the same area. As explained further below, AMF will take steps to bring the issue of competing MMNS systems to the proper

standards committee in order to establish a protocol that will allow multiple systems to operate within the same area.

C. Spectrum Within The 413-457 MHz Band Is Ideally Suited To Support New Wideband MMNS Devices

In view of the lack of available licensed or unlicensed spectrum and the unique technical requirements of wideband MMNS devices, AMF has identified the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands as ideally suited to support MMNS operation on a secondary basis. These frequencies are within the range of spectrum widely viewed as most suitable for RF signal propagation within the human body. In fact, AMF-conducted tissue tests confirm that frequencies near 400 MHz are optimal for RF signal propagation through body tissue. Moreover, because power consumption increases with the operating frequency, operation in the upper 400 MHz band and above would consume substantially more power than is acceptable. Thus, operation at frequencies near 400 MHz would allow battery-powered implant devices to conserve battery power and prolong battery life, all of which inure to the benefit of the patient, who will enjoy long-lasting, long-functioning systems.

Unlike most other spectrum options, use of the 413-419 MHz, 426-432 MHz, and 438-444 MHz bands appears to be limited to a few services, which, as further discussed in Section VI(A) below, will not be adversely affected by the operation of wideband MMNS devices. Specifically, the 413-419 MHz band is allocated for federal government fixed, mobile, and space research services,²³ but is used primarily by federal agencies for non-tactical land mobile

²³ See 47 C.F.R. § 2.106. Under footnote US13 of the Table of Frequency Allocations, 12.5 kHz-wide channels within the band also are available for assignment to non-government fixed stations for transmitting hydrological and meteorological data in cooperation with federal

operations.²⁴ Additionally, the 426-432 MHz and 438-444 MHz bands are allocated for federal government radiolocation services on a primary basis and for amateur services on a secondary basis.²⁵ Radiolocation operations in the 426-432 MHz and 438-444 MHz bands generally are limited to the military services, but these bands may be used by federal agencies for long-range surveillance radars that operate with very high power and wide bandwidths.²⁶

The 451-457 MHz band is allocated for non-government fixed and land mobile services.²⁷ Designating a fourth channel for MMNS in this band could mitigate any concerns regarding potential harmful interference that possibly could be caused by federal government radiolocation operations below 450 MHz. The availability of this additional spectrum could allow wideband MMNS systems to move to a fourth channel in the event that they are unable to operate on the other three channels as a result of harmful interference from government radiolocation operations below 450 MHz.

Finally, allocation of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands on a secondary basis for new wireless wideband medical devices would be consistent with international spectrum allocations. In all or substantial portions of the three

agencies, but the FCC licensing database indicates that only one non-government, non-experimental license has been issued. *See* 47 C.F.R. § 2.106 n.US13.

²⁴ *See* National Telecommunications and Information Administration, Federal Long-Range Spectrum Plan, at 77 (Sept. 2000) (“NTIA Spectrum Plan”), <http://www.ntia.doc.gov/osmhome/LRSP/Final-LRSP.pdf>.

²⁵ *See* 47 C.F.R. § 2.106. Under footnote US230 of the Table of Frequency Allocations, non-government land mobile radio services are permitted to operate on certain frequencies within the 422-430 MHz band, but these operations are limited to areas within 50 miles of Buffalo, New York; Detroit, Michigan; and Cleveland, Ohio. *See* 47 C.F.R. § 2.106 n.US230.

²⁶ *See* NTIA Spectrum Plan, at 77-79. The 426-432 MHz and 438-444 MHz bands also may be used by the military and the National Aeronautics and Space Administration for telemetry and telecommand. *Id.*

²⁷ *See* 47 C.F.R. § 2.106.

International Telecommunication Union regions, the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands are allocated to mobile, except aeronautical mobile, services on a primary basis.²⁸ International harmonization of this spectrum would expedite global deployment of new wireless wideband medical devices at reduced costs, and would allow patients using these devices to travel domestically and internationally with greater assurance that the devices will operate properly and within legal guidelines wherever they may be.

V. THE COMMISSION SHOULD ADOPT SERVICE RULES TO ACCOMMODATE THE TECHNICAL REQUIREMENTS FOR WIDEBAND MMNS DEVICES

To accommodate the technical requirements of wideband MMNS devices, the Commission should adopt service rules as set forth in Appendix A. Consistent with the licensing approach adopted for MICS and WMTS under Part 95 of the Commission's rules, the proposed MMNS rules provide for a "licensing by rule" framework. As the Commission previously found, a "licensing by rule" framework "will minimize regulatory procedures and thus facilitate deployment" of new wireless medical devices.²⁹ Additionally, consistent with the general structure of the service rules for MICS and other Part 95 services, the proposed MMNS rules specify technical requirements (including transmitter power limits, out-of-band emission limits, channel frequencies, channel bandwidth, and frequency monitoring capability) that are designed to accommodate the operation of MMNS devices and to mitigate the risk of harmful interference to and from other authorized services.

As explained in Section IV(B) above, the design of MMNS systems requires at least four channels, each of which is nearly 5 MHz wide. To minimize the size of the batteries, the system

²⁸ See 47 C.F.R. § 2.106, n.5.276.

²⁹ See *Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service*, 15 FCC Rcd 11206, ¶ 27 (2000).

must transmit and receive large amounts of data for very short periods of time. A wider channel bandwidth therefore is necessary to permit data transmissions during these very limited periods.

Each implantable microstimulator is designed to operate at a maximum effective isotropic radiated power (“EIRP”) of 200 microwatts. Each MCU is designed to operate at a maximum EIRP of 1 milliwatt.³⁰

Each MCU controls the timing of all communications with each patient’s implanted microstimulators, and all implanted microstimulators synchronize to the MCU. Once the MCU assigns the time slots for the downlink and uplink data packets to each of the implanted microstimulators in the network, each microstimulator turns on its receiving or transmitting circuitry for only a few microseconds at the assigned times in order to conserve battery power. Specifically, each implanted microstimulator transmits data for approximately 5 microseconds every 11 milliseconds and receives data for approximately 6 microseconds every 11 milliseconds (*i.e.*, less than 0.05 percent transmit duty cycle). For a system with 10 to 20 implanted microstimulators, the transmit duty cycle of the MCU is approximately 3 percent.³¹ As further discussed in Section VI(A) below, this low duty cycle serves to mitigate the risk of harmful interference to other authorized services.

VI. THE PROPOSED OPERATION OF WIDEBAND MMNS DEVICES WILL MITIGATE THE RISK OF HARMFUL INTERFERENCE AND PROTECT PATIENT SAFETY

As discussed in Section IV above, use of the 413-419 MHz, 426-432 MHz, and 438-444 MHz, bands appears to be limited to a few services, which will not be adversely affected by the

³⁰ See App. A (Proposed Rules for the Medical Micropower Network Service) at 6 (Sec. 95.639).

³¹ A typical MMNS system is expected to require less than 20 microstimulators. For example, based upon clinical work to date, a typical arm rehabilitation would require only six to eight microstimulators.

operation of wideband MMNS devices. These frequency bands are used primarily for federal non-tactical land mobile operations, military radiolocation operations, federal long-range surveillance radars, and amateur services (on a secondary basis). The 451-457 MHz band is primarily used by non-governmental fixed and land mobile radio services. As demonstrated in the attached engineering statement (Appendix C), wideband MMNS devices pose virtually no risk of harmful interference to the most prolific of these services. Moreover, wideband MMNS devices can be designed to avoid harmful interference from other authorized services and to protect patient safety.

A. Mitigation Of Harmful Interference To Other Authorized Systems

Under the proposed service rules, wideband MMNS devices can operate without causing harmful interference to other authorized services. As an initial matter, the Commission can protect existing authorized services by requiring MMNS devices to operate only on a secondary, non-harmful interference basis. Moreover, the attached engineering statement demonstrates that MMNS systems will not cause harmful interference to mobile, fixed, and amateur radio receivers in the 413-457 MHz band.³²

³² The attached engineering study does not assess the risk of harmful interference to military radiolocation operations and federal long-range surveillance radars in the 426-432 MHz and 438-444 MHz bands because the technical specifications for these systems do not appear to be publicly available. These radar systems, however, are expected to overcome any interference received from MMNS systems based upon the low power operation of the MMNS systems and upon their expected distance from the radar systems. The attached engineering study also does not address the risk of harmful interference to federal space research service in the 413-419 MHz band. Under footnote 5.268 of the Table of Frequency Allocations, federal space research service in this band “is limited to communications within 5 km of an orbiting, manned space vehicle.” In addition, the space research service may not “claim protection from, nor constrain the use and development of, stations of the fixed and mobile services.” See 47 C.F.R. § 2.106 n.5.268. Thus, federal space research service systems will not be remotely close to MMNS systems and consequently are highly unlikely to receive harmful interference.

The maximum transmitter power of an MMNS system (*i.e.*, 1 mW or 0 dBm for the MCU) is much lower than that of other higher-power systems in the 413-457 MHz band, thus virtually eliminating the risk of harmful interference to those services. Because other authorized systems operate at substantially higher power levels, they will be able to overcome any interference received from low-power MMNS systems.

Additionally, AMF's MMNS devices transmit for only a small fraction of the available time. Specifically, the duty cycle of the MCU is approximately 3 percent for a system with 10 to 20 implanted microstimulators. This low duty cycle effectively limits the average power available for interference to a few percent of that of a continuously operating transmitter.

Furthermore, the wideband operation of MMNS systems further reduces the risk of harmful interference to government and non-government land mobile systems, as well as government radiolocation systems, most of which are believed to employ narrowband technology. These narrowband systems contain front-end filters in their receivers that typically use a 5 kHz passband and consequently will receive only 0.1 percent of the power transmitted by an MMNS system.

The attached engineering statement demonstrates that at a distance of 30 meters or greater, the interference from MCU transmissions is below the mobile radio receiver noise floor, and therefore mobile radio receivers generally cannot discern the presence of MCU signals. The engineering statement further concludes that the interference from MCU transmissions would exceed the mobile radio receiver noise floor only in the unlikely event that an MCU is operating at a distance of 3 meters from a mobile radio receiver. In that event, however, the interference could be mitigated by (1) adjusting the orientation or alignment of the MCU or the mobile radio antenna; (2) increasing the distance between the MCU and the mobile radio receiver; or (3)

creating an obstruction in the line of sight path, such as by moving the MCU closer to the patient's body. Moreover, through its frequency monitoring capability, the MCU can shift to a less congested channel, thus further reducing the risk of harmful interference to nearby mobile radio receivers.

B. Mitigation Of Harmful Interference From Other Authorized Systems

AMF's highest priority is to design wideband MMNS systems to ensure patient safety in the event of a communications failure. As an initial matter, MMNS systems will not be used to treat disorders that could result in harm to the patient if the system communications were disabled for a period of time. For the myriad of other neuromuscular disorders for which MMNS systems will be used to treat, various interference mitigation strategies can ensure patient safety. These mitigation strategies are two-fold. One strategy addresses possible harmful interference from incumbents in the relevant frequency bands, and another mitigation approach addresses possible interference between MMNS systems operating in the same frequency bands.

In order to address interference from incumbent users, MMNS systems, for example, use multi-bit coding designed to operate in a noisy environment. By transmitting redundant bits, this coding technique permits detection and correction of data transmission errors. This coding technique is one of the primary mechanisms used by the system to ensure proper functioning and to prevent transmission of erroneous signals corrupted by interference noise that otherwise would cause the system to malfunction.

MMNS systems also can employ a technique to assess channel occupancy and interference prior to and while occupying a channel. If harmful interference is detected on a particular channel, the system can be instructed not to communicate on that channel.

Additionally, MMNS systems could detect each other's presence by monitoring for specially coded beacon messages contained in the MCU-transmitted signal. AMF is exploring the establishment of an industry-led standards committee to determine an appropriate communications protocol that can be used by all MMNS devices to mitigate the risk of interference and ensure competition in these frequencies, thus maximizing the number of people who will have access to this revolutionary technology.

VIII. CONCLUSION

Based upon the foregoing, AMF urges the Commission to grant this petition and commence a rulemaking to adopt appropriate rules to facilitate deployment of new wideband MMNS devices. These devices represent breakthrough medical technology that is available now and that will materially improve the quality of life for millions of Americans with disabilities previously considered untreatable or very difficult to treat.

Respectfully submitted,

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