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

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| **In the Matter of** | **)** | |
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| **Amendment of Parts 2 and 95 of the** | **)** | **ET Docket No. 09-36** |
| **Commission's Rules to Provide Additional** | **)** | |
| **Spectrum for the Medical Device** | **)** | |
| **Radiocommunication Service in the 413-457** | **)** | |
| **MHz Band** | **)** | |

**To: The Commission**

## COMMENTS OF ARRL, THE NATIONAL ASSOCIATION FOR AMATEUR RADIO

ARRL, the national association for Amateur Radio, also known as the American Radio Relay League, Incorporated (ARRL), by counsel and pursuant to the *Notice of Proposed Rule Making*, FCC 09-36, 74 Fed. Reg. 22491, released March 12, 2009 (the Notice), hereby respectfully submits its comments relative to the Commission's consideration of the feasibility of allowing up to 24 megahertz of spectrum in the 413-457 MHz band to be used on a secondary basis under the Medical Device Radiocommunication Service (MedRadio Service) in Part 95 of the Commission's Rules. The Notice was issued in response to the September 5, 2007 Petition for Rule Making filed by the Alfred Mann Foundation (AMF) which manufactures and wishes to market wide bandwidth, implantable neuromuscular microstimulation devices using wireless technologies. The Notice proposes to permit these and other devices, referred to collectively as wideband medical micropower networks (MMN) such as the neural stimulators to permit patient mobility following injury or damage to a patient's neuromuscular and other systems. In the interests of the Amateur Radio Service in

continued access to the 420-450 MHz band for the provision of effective emergency and public service communications, and in the interest of avoiding interference to these MMN devices and harm to the patients utilizing them, ARRL states as follows:

## I. Introduction

1. ARRL's interest in this proceeding is principally with respect to the interference susceptibility of devices which might be utilized in the MedRadio Service pursuant to any rules [1] promulgated pursuant to the Notice. ARRL does not question the public interest benefits of MMNs such as those developed by AMF. It is noteworthy that AMF has been forthcoming with ARRL representatives when asked about the specifics of the devices manufactured by AMF, and particularly with respect to the design of their devices relative to interference susceptibility.[2] As well, ARRL is generally satisfied, and with but a single caveat, agrees with the Commission's conclusion at paragraph 23 of the Notice, that MMN devices as designed by AMF are unlikely to *cause* interference to stations in the Amateur Service, individually or in the aggregate, if operated on a secondary basis to authorized radio services (including the Amateur Service) in the 426-432 MHz and 438-444 MHz segments.[3] This conclusion is premised on the configuration

[1] As is discussed below, the Notice in this proceeding does not contain an Appendix of proposed rules for this service. This is unfortunate in this proceeding in particular, where an incorrect allocation decision by the Commission could create substantial harm to patients who are utilizing the devices. While ARRL is as favorably disposed to the concept of MMNs as is the Commission, it appears that the Commission has insufficient information about them to proceed with a Notice of Proposed Rule Making. It is strongly urged that, prior to authorizing MMNs in this proceeding, the Commission publish a proposed appendix of rules under which MMNs would operate, and seek comment on them.

[2] In February of this year, ARRL representatives met with representatives of AMF concerning the RF susceptibility of the MMN devices, including neural implant devices and the body-worn Master Control Unit (MCU). AMF's staff explained the multiple levels of interference avoidance and rejection design in their devices.

[3] The Commission stated, accurately in ARRL's view, that, "(g)iven the low transmitter power and duty cycle limits that would typically be used by either the implanted MMN device or the external MCU, we expect that the risk of interference to MMNs to incumbent operations in these frequency bands would be negligibly small." That said, no testing has been done to verify this conclusion, and such testing should be concluded and the results analyzed before this anticipatory conclusion can be relied upon.

of the AMF neural stimulator devices specifically, however, and would not necessarily apply to any other MMN devices which might be authorized as a result of this proceeding. The Commission describes the implantable microstimulator devices as operating at a maximum EIRP of 200 microwatts, and asserts that the MCU would be limited to a maximum EIRP of 1 milliwatt. In addition to the relatively low power levels of these devices, the implanted MMN transmitters would be expected to transmit data for 5 microseconds every 11 milliseconds, and receive data for approximately 6 microseconds every 11 milliseconds. Therefore, for a system with 10 to 20 implanted microstimulators, the transmit duty cycle of the MCU would be approximately 3 percent. There is no indication, of course, what interference effects would result if larger numbers of microstimulators are permitted in a particular patient.

2. This proceeding is one in which it would have been helpful to have an Appendix of proposed service rules governing the use of MMNs contained in the Notice. As it is, inasmuch as the Commission did not include a proposed Appendix, the interference issues are difficult to address. Interference susceptibility of MMNs and interference potential from MMNs to incumbent services are dependent on a number of factors, and the AMF devices are only one example of the types of devices that might be marketed and utilized pursuant to rules adopted in this proceeding. Unless the rules governing MMNs incorporate as limits the technical parameters and operating limits of the AMF devices specifically, incumbent licensees are forced to speculate in this proceeding about the interference potential to and from an unknown universe of MMNs relative to licensed radio services. At paragraph 26 of the Notice, for example, the Commission notes that its central focus is on MMNs used to provide functional electronic

stimulation (FES) therapeutic treatment and the kinds of devices described by AMF. But it asks for comment on other types of FES applications that would be consistent with MMN operation and that would similarly require the wider emission bandwidth available in this spectrum. As discussed below, because the interference potential and the interference susceptibility of such devices (related to AMF devices only by function and bandwidth requirements) might vary widely, this Notice is not sufficiently specific to allow the determination of proper rules to address the operation of a devices other than those which utilize the AMF architecture and operating parameters. It is therefore suggested that the comments received in this proceeding be used to develop a Further Notice of Proposed Rule Making so that the operating parameters applicable to all MMN devices can be accurately and properly determined.

**II. Allocation Considerations and Alternative Bands**

3. The Commission begins its discussion of the propriety of the use of segments of the band 413-457 MHz at paragraph 17 of the Notice with the question of the suitability of this band "for use by medical micro-power networks or other similar bandwidth intensive medical implant networks *that require a high degree of operational reliability*." (Emphasis added). Viewed from this perspective, the band 420-450 MHz (and more specifically the segments 426-432 MHz and 438-444 MHz) is not a good candidate band for the purpose. The Notice at Paragraph 18 contains a detailed explanation of the use of this band for government facilities, but makes only a passing reference to the fact that the Amateur Service has a secondary allocation at 420-450 MHz.

4. Amateur Radio operation at 420-450 MHz includes a wide variety of facilities with varied configurations, typical power levels, and emission types. However, Amateur fixed, mobile and portable facilities are operated on a ubiquitous basis, often at very high power levels, and in environments that range from rural to urban, commercial and industrial to residential, and therefore must be assumed to be located in very close proximity to persons using implanted MMN devices. AMF contends, perhaps accurately, that "no other suitable spectrum is now available to accommodate the operation of MMNs." Part of this conclusion is that the bands above 470 MHz that are available in the Wireless Medical Telemetry Service (WMTS) under Part 95 (which includes, among other bands, 608-614 MHz) are unsuitable because radiofrequency signal propagation within the human body is not satisfactory above 470 MHz. [4] Though there is Part 90 spectrum above 450 MHz available under Part 90 for low-power biomedical telemetry,[5] AMF argues that bands between 450 and 470 MHz are unsuitable due to the fact that the band is "congested and populated with commercial, high-power transmitters that could preclude reliable operation of lower-power, wireless medical implant devices." This is a very worrisome contention, and not the argument that should be made by the proponent

[4] Notice, at ¶ 21. ARRL is not satisfied with this unsupported allegation. Furthermore, the Commission has been down a very similar road before, with respect to medical devices in the band 460-470 MHz. Secondary use of the 460-470 MHz band by low power medical devices was authorized in 1973. This resulted in restrictions in the power levels permitted for land mobile radio stations. The Commission, in response to instances of interference to low power medical devices from normally operating land mobile radio facilities, established the Wireless Medical Telemetry Service (WMTS) in 1999. There followed a long period of migration of low power medical devices from the 460-470 MHz band to the WMTS frequencies in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands. Those operations that remained in the UHF band became secondary to the land mobile service. It seems prudent to consider avoiding the precise problems that plagued low power medical devices and require that MMNs utilize WMTS spectrum which was established precisely for the purpose of accommodating medical devices such as MMNs, rather than the 413-457 MHz band, which accommodates a plethora of high-power fixed and mobile radio services that might disrupt medical devices implanted in patients. Anyone asserting that the 608-614 MHz band is insufficient as a substitute for the band 413-457 MHz should be asked to justify the assertion as a technical matter.

[5] Id.

of a new service that is secondary to other incumbent licensees. ARRL contends that if the 450-470 MHz band hosts services that are incompatible with reliable operation of MMNs, then the 420-450 MHz band, and especially the segment proposed for MMNs at 438-444 MHz is equally incompatible with MMNs. Amateur Radio television transmitters and repeaters and FM voice repeater input and outputs operate in this segment in particular, and the potential for interference to MMNs is on the same order, or worse, than would be the case if MMNs were to operate in the Part 90 biomedical telemetry band between 450 and 470 MHz. In the segment 426-432 MHz, Amateur television stations transmit on a wide bandwidth basis. Amateur Radio stations are permitted to operate at power levels up to 1500 watts PEP output, and the RF environment at 420-450 MHz, with primary government radiolocation facilities and high-power Amateur facilities is no more conducive to reliable MMN operation than would be the 450-470 MHz band.

5. Finally, it is not clear from the Notice what the allocation status of MMNs would be relative to Amateur Radio stations. Though AMF proposed that MMNs would be secondary to incumbent licensed operations in the subject bands, the Amateur Service is presently secondary to government radiolocation in this band (which represents a cooperative sharing arrangement that is satisfactory to both government agencies and the Amateur Service). While it is presumed that the proposal is for MMNs to be secondary to both government radiolocation and to the Amateur Service (as opposed to Amateur stations and MMNs being co-secondary) this is not clear from the Notice. Because the interference susceptibility of MMN devices generally is not known, it would be improper to create a co-secondary allocation for MMNs anywhere in the 420-450 MHz band at this

time. The Amateur Service has a practical inability to protect patients wearing RF-susceptible MMNs from interference from ongoing Amateur operations in the 420-450 MHz band, and therefore all MMN operation is going to have to be conditioned on the ability to withstand and operate in the presence of such high-power signals, and thus *subordinate* in allocation status to the Amateur Service. Unless this interference rejection capability is demonstrated by MMN proponents in advance, the devices should not be allowed to operate anywhere in the 420-450 MHz band.

6. A letter (with attachments) appears in the docket file dated February 2009 addressed to the Chief, Office of Engineering and Technology from Mr. Karl Nebbia, Associate Administrator, Office of Spectrum Management, NTIA. Enclosure #2 of that letter addresses technical issues related to the electromagnetic compatibility between MMN devices and federal systems that should be addressed as part of the instant rulemaking proceeding. Mr. Nebbia states that, because of the wide variety of Federal systems operating in the band (including land mobile radio systems), with widely varied power levels and bandwidths, MMN error detection and coding techniques, for example, may work well for one type of interfering device and not well for others. Mr. Nebbia also states:

> There are no analytical techniques that can be employed to assess the effectiveness of an interference mitigation technique. Measurements are necessary to verify that the interference mitigation techniques will actually protect the MMN service systems and the individuals that rely on them. To accomplish this, coordinated measurement efforts with the incumbent spectrum users are necessary. The authorization of the MMN service will be subject to the successful completion of measurements that verify the interference mitigation techniques employed protect MMN Service devices from incumbent systems.[6]

[6] See, NTIA Letter dated February 27, 2009, Enclosure 2, *Technical Issues Related to Electromagnetic Compatibility Between Medical Devices and Federal Systems in the 413-450 MHz Band.*

ARRL agrees with this conclusion. The Commission has proposed to authorize this new radio service, which promises relief for many Americans suffering from spinal cord injuries, strokes and the like, but it has very little information about the potential for harm to MMN patients from interference to operational MMNs from incumbent radio services, or the likelihood of the same. While ARRL's discussions with AMF have provided some understanding of the interference potential and susceptibility of AMF's version of MMNs, it is suggested that the allocation proposed herein is premature because (1) measurements that verify the interference mitigation techniques employed protect MMN service devices from incumbent systems have not yet apparently been conducted, or if conducted, the results have not yet been published or evaluated; and (2) the characteristics of systems other than those of AMF have not yet been identified, and therefore rules that would govern those operations, and their interference potential and susceptibility, cannot be confidently promulgated.

## III. Interference From MMNs to Amateur and Amateur-Satellite Service Stations at Parameters Proposed By AMF Appears to be Generally Manageable.

7. The above concerns notwithstanding, the combination of the low EIRP levels and the relatively low duty cycle of AMF makes interference from those devices in particular to Amateur Radio communications in the 420-450 MHz band unlikely generally, with the exception of the segments of the 420-450 MHz band used for narrowband, weak-signal terrestrial and Earth-moon-Earth communications and international Amateur Satellite Service communications between 432 and 438 MHz.[7]

[7] AMF described the architecture of their MMN system at 413-457 MHz to ARRL as follows: There are four, 5 MHz channels; one below 420 MHz, one above 450 MHz, and two within 420-450 MHz. The segment near 432 MHz was deliberately excluded by AMF due to concerns expressed to AMF long ago about use by Amateur stations utilizing high transmitter power for Earth-Moon-Earth and weak-signal

Avoiding this segment (which the AMF devices do in their channel configuration)[8] as proposed in the Notice will reduce the interference potential from MMN and MCU devices to sensitive receivers used in the 432-438 MHz band for terrestrial weak-signal communications and satellite communications.

8. The Commission, at Paragraph 17 of the Notice, asks for consideration of the suitability of four segments of the 413-457 MHz band for MMNs "or other similar bandwidth intensive medical implant networks that require a high degree of operational reliability." In terms of interference to Amateur and Amateur Satellite Service stations from these devices, ARRL is satisfied that devices similar to the AMF devices will not predictably cause interference to Amateur receivers, if they are operated in the segments 426-432 MHz or 438-444 MHz at the power levels discussed above, and that in those band segments, any interference to an Amateur receiver can be addressed on a case-by-case basis. The segment 432-438 MHz should be excluded, however, as AMF has done, and as the Commission proposes at paragraph 22 of the Notice, in order to avoid interference to sensitive Amateur Service and Amateur Satellite Service receivers operated in that segment.

9. Separation distances between MMFs and Amateur Radio stations vary widely due to the changing locations of persons utilizing MMF devices and the ubiquitous, mobile and portable nature of modern Amateur Radio operations. Geographic separation therefore cannot be relied upon as an interference mitigation factor in this context. Neither has ARRL undertaken a study of the aggregate interference potential of

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narrowband operation. It is requested that the segment 432-438 MHz be specifically excluded from any allocation, whether or not secondary to the Amateur Service, to the MedRadio service.

[8] The AMF Petition for Rule Making stated, at page 14 that AMF intended to use the segments 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz, thus excluding the segment 432-438 MHz.

implanted MMF devices, assuming a large number of implanted devices in a particular patient. It must be assumed as well that the relative locations and proximities of Amateur stations and patients with implanted MMN devices are not known and therefore not subject to prior, or real-time, coordination.

10. Exclusion of the 432-438 MHz segment from the bands which might be made available for MMN devices will also help to reduce the potential of such devices to malfunction in the presence of nearby, high-power Amateur Radio transmitters operated in those same segments. Indeed, interference to MMF devices from authorized services in the 413-457 MHz band is by far the larger concern.

**IV. Interference Susceptibility of MMNs Must Be Carefully Regulated**

11. The Commission states at Paragraph 24 of the Notice that, given the "wide range of incumbent operations in the 410-460 MHz band, (it) believe(s) that there is some potential for high power incumbent stations to cause interference to MMNs. In addition to high power, other factors such as separation distances and field of view could compromise MMN operations." It goes on to note that there are various characteristics of MMN architecture that might mitigate this interference susceptibility. Indeed, AMF has discussed these characteristics with ARRL. There are levels of interference avoidance design in the devices designed by AMF. While ARRL is not aware of any field tests of the devices in the presence of typical RF signals found in the 413-457 MHz band, ARRL is cautiously optimistic about the ability of MMNs to avoid interference and avoid harm to patients in the process. However, no rules should be enacted without a comprehensive series of field tests that assure patient safety in the presence of typical RF fields in the bands at issue in this proceeding.

12. Furthermore, the interference rejection mechanisms, in order to be effective, would have to be required for all MMNs. As these techniques have been explained to ARRL, the AMF system consists of small body-implanted devices called bions that deliver neural impulses (for example, to stimulate arm or leg movements). The MCU sends header messages to the bions, and the bions talk back to the MCU in short bursts. Three levels of interference protection exist relative to noise on the frequency or in the presence of high-power signals. The first is the attenuation of external noise due to the shielding of the human body, which provides 30 dB (plus or minus 10 dB) of attenuation between the exterior of the body and the bions. The second is coding. The coding is a 2-to-one system. There are 30 bits in each transmission. Fifteen are data bits and fifteen are error correction bits for handshaking between the MCU and the bions. If there are six bits of change, the MCU will detect this and trigger an error message. As a practical matter, if there is interference in up to 250 kHz of the 5 MHz bandwidth of the transmission, there will not be any errors in the communication between the MCU and the bions, and the handshaking will work nevertheless. The system uses quadphase modulation which is very noise-resistant.

13. While there is no attenuation of external noise in the MCU from the human body, since the MCU is worn outside, there are filters, which notch interference based on a memory. So, if the system begins operating on a channel and a signal arises within the operating bandwidth, the filters will notice the difference and notch the offending signal out. Notches are up to 250 kHz bandwidth each. Numerous notches can be implemented simultaneously and use the same channel. If there are too many notched segments, the MCU will trigger a channel change. Dynamic channel selection is the last interference

protection mechanism. The MCU scans all 4 channels 30 times per second, and can shift to an unoccupied channel extremely quickly. Finally, there is a failsafe mode. If there is no communication at all between the MCU and the bions, the bions function in such a way as to permit the neuron triggering on a low-level basis that apparently allows, for example, limb movement.

14. Given the redundancy in the system design relative to interference rejection; and subject to appropriate, publicly available measurements which in fact validate the concepts; and subject further to the incorporation of all aspects of this interference rejection mechanism in rules governing MMNs such that they are required for all devices operating pursuant to the rules governing MMNs in the 420-450 MHz band, ARRL would be satisfied that this design of the devices could protect patients with some redundancy, in the presence of noise or interfering narrowband, and probably wideband, signals. This redundancy is dependent upon the availability of all four channels for MMNs, permitting the MCUs to shift the channel (without delay or interruption of the implanted MMN devices' functions) to one more suitable to the RF environment as needed. The availability of the two channels outside the 420-450 MHz band, in addition to those at 426-432 MHz and 438-444 MHz, is critical for patient protection.

15. The public's perception of the safety of these devices in the presence of RF fields is almost as important as the actual level of safety. The Commission should require that MMN devices, in order to operate in the 420-450 MHz band, be designed to reject any and all unwanted co-channel and adjacent channel signals from government radiolocation stations and Amateur Radio stations, and require that the manufacturers or retailers of all MMN devices provide in patient literature clear, unequivocal statements

providing adequate assurances that the devices *will not malfunction* in the presence of strong, high-power signals from authorized radio services.

16. Radio amateurs have in the past been subjected to operating restrictions premised on bare allegations of interference with the operation of medical devices, including heart pacemakers. These allegations are often a subterfuge; the underlying, real motivation for the complaint often being interference to RF-susceptible home electronic equipment. However, it is important to assure patients and the general public that MMN devices for use in the 413-457 MHz band are specifically designed to operate, and they can operate in close geographic proximity to licensed Amateur Radio stations operating in the 420-450 MHz band without malfunction and without risk to the implant patient. The patient should also be given information about the means by which these devices are able to operate normally in the presence of high-powered, licensed radio services on the same frequencies, including: (1) attenuation of external noise due to the implant of the neural stimulators in the human body; (2) the use of error correction in the coding and the ability to sense even minor bit errors; (3) filtering in any externally worn master control unit; and (4) dynamic channel selection. Information to the patient about the failsafe mode should also be required. The patient should be informed that these redundant layers of protection are both required by Commission rules and are sufficient, without more, to protect the patient. Most importantly, the patient should be informed that there is no need to restrict the operation of any Amateur Radio station operating in the 420-450 MHz band or otherwise. Amateur stations should be allowed to operate at power levels permitted by Commission regulations without any concern for electromagnetic incompatibility with MMNs, and without any risk of harm to the patient. It is strongly recommended that the

Commission include contention protocol requirements that incorporate these same interference rejection characteristics for all MMN devices operating under Part 95 in the 420-450 MHz band.

## V. Miscellaneous Issues

17. At paragraph 50 of the Notice and thereafter, the Commission asks a series of questions about MMN devices, but again, it proposes no specific rules. ARRL suggests as follows with respect to several of these: First, each MMN transmitter, in order to be used for patients who reside in or who may travel to the United States or its territories should be subject to the Commission's equipment authorization (certification) process. This should include careful regulation of written information provided to patients and medical providers regarding interference susceptibility and the immunity of the devices to radio frequency interference from all sources in the bands 413-457 MHz. The disclosure statement and labeling language proposed in Paragraphs 53 and 54 of the Notice are *insufficient* for the purpose. The simple disclaimers and normal Part 15-type notices (to the effect that that there is no guarantee that the device will not receive interference or that the transmissions will not be blocked by interference, and that the operation of the devices is subject to non-interference and interference acceptance conditions), is an abdication of (and is no substitute for fulfillment of ) the Commission's obligation to medical patients to place MMN devices in a band in which the devices *will not* receive harmful interference, and to insure that they will not malfunction in the presence of strong RF signals. If that assurance cannot be had, then the Commission clearly should not place these devices in the 413-457 MHz band in the first place.

18. The Notice asks at paragraphs 48 and 52 what the appropriate limits are of the use of such devices. ARRL suggests that only portable, body-worn MMN devices should be permitted. No fixed antenna is appropriate in the frequency range proposed. One basic reason for the low power of the implanted MMNs and the low power of the belt-worn MCU is the close proximity of one to the other in the AMF iteration of the devices. Any increase in geographic separation between the two devices increases both the interference potential and the interference susceptibility of the devices.

## VI. Conclusions

19. ARRL believes that the choice of frequency bands for MMNs in this Notice is unfortunate and unnecessary, and that the WMTS offers a far more suitable solution than does the 413-457 MHz band for MMNs. The Alfred Mann Foundation has developed an MMN system that utilizes operating parameters which, in general, do not appear to create a significant source of interference to licensed radio services, including the Amateur Service, in the band segments 426-432 MHz or 438-444 MHz. Because of redundant interference rejection design, the AMF devices appear to have some reasonable prospect of avoiding the disastrous consequences of RF interference to implanted MMNs. The Commission should not, however, permit the marketing of MMNs or any similar device in the 420-450 MHz band: (1) unless and until thorough RF interference susceptibility testing is conducted on the AMF devices relative to high power Amateur Radio equipment; (2) at parameters other than those inherent in the AMF system, which incorporates notably redundant interference rejection design characteristics; and (3) without very specific patient notifications and labeling of the body-worn MCUs and other

portable components which provide firm assurance that the devices will not malfunction in the presence of RF fields from authorized radio services in the same bands.

Therefore, the foregoing considered, ARRL, the National Association for Amateur Radio, respectfully requests that the Commission make the proposed changes with respect to the 420-450 MHz band only in accordance with the accommodations recommended herein.

Respectfully submitted,

**ARRL, the National Association For Amateur Radio**

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