Federal Communications Commission
Washington, D.C. 20554

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Small Entity Compliance Guide

Medical Micro-Power Networks

Report and Order
FCC 11-176
WT Docket No. 09-36; RM-11404
Released: November 30, 2011

This Guide is prepared in accordance with the requirements of Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It is intended to help small entities—small businesses, small organizations (non-profits), and small governmental jurisdictions—comply with the new rules adopted in the above-referenced FCC rulemaking docket(s). This Guide is not intended to replace the rules and, therefore, final authority rests solely with the rules. Although we have attempted to cover all parts of the rules that might be especially important to small entities, the coverage may not be exhaustive. This Guide may, perhaps, not apply in a particular situation based upon the circumstances, and the FCC retains the discretion to adopt approaches on a case-by-case basis that may differ from this Guide, where appropriate. Any decisions regarding a particular small entity will be based on the statute and regulations.

In any civil or administrative action against a small entity for a violation of rules, the content of the Small Entity Compliance Guide may be considered as evidence of the reasonableness or appropriateness of proposed fines, penalties or damages. Interested parties are free to file comments regarding this Guide and the appropriateness of its application to a particular situation; the FCC will consider whether the recommendations or interpretations in the Guide are appropriate in that situation. The FCC may decide to revise this Guide without public notice to reflect changes in the FCC's approach to implementing a rule, or to clarify or update the text of the Guide. Direct your comments and recommendations, or calls for further assistance, to the FCC's Consumer Center:

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Medical Micro-Power Networks

1. Objectives of the Proceeding

In the *Report and Order* adopted November 30, 2011 in ET Docket 09-36, the Commission amended the Part 95 rules governing MedRadio devices to enable networks of implanted medical devices called medical micropower networks. Medical micro-power networks, or MMNs for short, are networks of devices implanted within the human body that communicate with a programmer/controller device outside the body using a wireless communication link. MMNs are used for the purpose of providing functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

The existing MedRadio rules under Part 95 of the Commission's rules allow implanted and body-worn medical devices to operate in the 401-406 MHz band. The *Report and Order* amends the MedRadio rules to allow MMNs to operate in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands on a secondary basis. These frequency bands are used for other purposes on a primary basis such as Federal government and private land mobile radios, Federal government radars, and remote broadcast of radio stations. Because MMNs will operate on a secondary basis, they may not cause interference to and must accept interference from primary users of these frequency bands. Use of these four frequency bands for medical devices is limited only to MMNs. Other medical devices such as pacemakers, insulin pumps, hearing aids, and medical telemetry devices may not use these four frequency bands.

A copy of this *Report and Order* is available at:
http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-11-176A1.pdf

2. Definitions

MMNs are defined in the Part 95 rules as follows:

> An ultra-low power wideband network consisting of a MedRadio programmer/control transmitter and medical implant transmitters, all of which transmit or receive non-voice data or related device control commands for the purpose of facilitating functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

3. Restrictions on MMN Operation

Use of MMNs must comply with the following restrictions:

- MMNs can only be used to provide functional electric stimulation.
- MMNS can be used only for diagnostic and therapeutic purposes.
- MMNs must be provided to a patient only under the direction of a duly authorized health care professional.
- MMNs may not cause harmful interference to other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.
- MMNs must accept interference from other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

- MMN devices may not be used to relay information to other devices that are not part of the MMN using the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands.
- An MMN programmer/controller may communicate with a programmer/controller of another MMN to coordinate sharing of the wireless link.
- Implanted MMN devices may only communicate with the programmer/controller for their MMN. An MMN implanted device may not communicate directly with another MMN implanted device.
- An MMN programmer/controller can only control implanted devices within one patient.
- Multiple MMNs may be present within a patient.
- MMN transmitters must be certificated by the FCC or a Telecommunications Certification Body (TCB) designated by the FCC. To obtain certification the manufacturer must submit a certification application accompanied by a measurement report showing compliance with the FCC technical requirements to the Commission or TCB. See 47 C.F.R. § 2.1033 for the certification application requirements or http://www.fcc.gov/encyclopedia/equipment-authorization-procedures for more information.
- MMN devices are licensed by rule and as such, individual licenses are not required for MMN use.

4. Technical Requirements

MMNs must comply with a number of technical requirements designed to allow them to share the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands with primary users and other MMNs. Basically, these requirements require the MMNs to be frequency agile so that they can switch among the four frequency bands so as to continue operating when use of a particular frequency band becomes too heavy. The requirements also limit the power and length of time that MMNs may transmit. Specifically, these requirements are that:

- Each MMN programmer/controller and implanted device must be capable of operating in any of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands.
- The programmer/controller and implanted devices that are part of a single MMN must operate in the same frequency band.
- MMN programmer/controllers must have the ability to operate in the presence of other primary and secondary users in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands.
- An MMN programmer/controller must be capable of monitoring the frequency band in which it is operating at least once every second.
- An MMN programmer/controller must be capable of monitoring alternate frequency bands (*i.e.* the frequency bands on which it is not operating) within two seconds prior to executing a change to an alternate frequency band.
- If the MMN programmer/controller detects a signal lasting more than 50 milliseconds that has a power greater than -60 dBm as received by a 0 dBi antenna in any 12.5 kHz bandwidth within the authorized bandwidth of the MMN signal, the programmer/controller will move to another frequency band within one second.
- MMN transmitters are allowed a maximum emission bandwidth of six megahertz.
- MMN transmitters shall transmit with a peak EIRP of the lesser of 1 mW or (10 log B – 7.782) dBm, where B is the 20 dB emission bandwidth of the transmitted signal in megahertz. The peak power spectral density of the transmitted signal shall not exceed 800 microwatts per megahertz in any 1 megahertz band.
- In the first 2.5 megahertz beyond any of the frequency bands authorized for MMN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz

bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission. In addition, emissions from an MMN transmitter that are more than 2.5 megahertz beyond any of the frequency bands authorized for MMN operation must be less than field strength limits specified in the Part 95 rules.

- MMN programmer/controllers shall not transmit more than three percent of the time.

5. Labeling and Other Requirements

MMNs must comply with a number of other requirements designed to inform medical professionals about the secondary status of MMNs and allow the Commission to enforce the Part 95 rules governing MMN operation:

- All non-implanted MMN devices must be made available for inspection upon request by an authorized FCC representative.
- Persons operating implanted MMN transmitters are required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference.
- A disclosure statement as specified in the Part 95 rules must be included with each MMN transmitting device. This disclosure statement warns that the device must accept interference from and not cause interference to primary users sharing the same frequency bands. The statement also warns that there is no guarantee that the MMN device will not receive interference.
- The MMN programmer/control transmitters must be labeled with a statement as specified in the Part 95 rules. The statement warns that the device may not cause interference to and must accept interference from devices that are operating on a primary basis in the same frequency bands as the MMN programmer/control transmitter.
- MMN implant transmitters must be identified by a serial number that is assigned by the device manufacturer. This serial number may be placed either on the device or in the instruction manual for the transmitter.

6. Weblink and Citations

The *Report and Order* adopted November 30, 2011: Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz band, ET Docket No. 09-36, RM-11404, FCC 11-176 (Released Nov. 30, 2011). Available at:

http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-11-176A1.pdf

The *Notice of Proposed Rulemaking* that preceded the November 30, 2011 *Report and Order*: Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz band, ET Docket No. 09-36, RM-11404, *Notice of Proposed Rulemaking*, 24 FCC Rcd 3445 (2009). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-09-20A1.pdf

The *Notice of Inquiry* regarding medical devices which proceeded the *Notice of Proposed Rulemaking*: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket Nos. 06-135, 05-213, 03-92, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, 21 FCC Rcd 8164 (2006). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-06-103A1.pdf

A *Memorandum Opinion and Order* amending the Part 95 MedRadio rules: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket Nos. 06-135, 05-213, and 03-

92, *Memorandum Opinion and Order,* 25 FCC Rcd 10414 (2010). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-10-128A1.pdf

A previous small business compliance guide addressing the previous amendment to the MedRadio rules is available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-11-912A1.doc

The *Report and Order* which adopted the Part 95 MedRadio rules that were amended by the November 30, 2011 *Report and Order*: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket Nos. 06-135, 05-213, and 03-92, *Report and Order,* 24 FCC Rcd 3474 (2009). Available at http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-09-23A1.pdf

A previous small business compliance guide addressing the original MedRadio rules is available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-10-815A1.pdf