

APPENDIX B

Proposed Rules for Medical Micropower Network Devices

1. The Table of Frequency Allocations in Section 2.106 is amended by revising the entries for 410-420 MHz, 420-450 MHz, 450-454 MHz, 454-455 MHz, 455-456, and 456-460 MHz, and revising footnote US345 to read as follows:

International Table	United States Table		FCC Rule Part(s)
*****	Federal Table (MHz)	Non-Federal Table (MHz)	
*****	410-420 FIXED US13 MOBILE SPACE RESEARCH (space-to-space) 5.268 G5 US345	410-420 US13 US345	Private Land Mobile (90) Personal (95)
*****	420-450 RADIOLOCATION US217 G2 G129 5.286 US7 US87 US230 US397 G8 US345	420-450 Amateur US7 NG135 5.282 5.286 US87 US217 US230 US397 US345	Private Land Mobile (90) Amateur (97) Personal (95)
*****	450-454 5.286 US87 US345	450-454 LAND MOBILE 5.286 US87 US345 NG112 NG124	Auxiliary Broadcasting (74) Private Land Mobile (90) Personal (95)
*****	454-456	454-455 FIXED LAND MOBILE US345 NG12 NG112 NG148 455-456 LAND MOBILE US345	Public Mobile (22) Maritime (80) Personal (95) Auxiliary Broadcasting (74) Personal (95)
*****	456-460 5.287 5.288 US345	456-460 FIXED LAND MOBILE 5.287 5.288 US345 NG112 NG124 NG148	Public Mobile (22) Maritime (80) Private Land Mobile (90) Personal (95)

UNITED STATES (US) FOOTNOTES

US345 In the band 401–406 MHz, the mobile, except mobile aeronautical, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Device Radiocommunication Service (MedRadio) operations. In the band 413-419 MHz, the mobile, except mobile aeronautical, service is allocated on a secondary basis and is limited to MedRadio Medical Micropower Network (MMN) operations. MedRadio MMN

operations also are permitted in the bands 426-432 MHz, 438-444 MHz, and 451-457 MHz bands on a secondary basis. MedRadio stations are authorized by rule on the condition that harmful interference is not caused to stations in the meteorological aids, meteorological-satellite, and earth exploration-satellite, and other authorized services in the relevant frequency bands, and that MedRadio stations accept interference from stations in the meteorological aids, meteorological-satellite, earth exploration-satellite services, and other authorized services in the relevant frequency bands.

2. Section 95.628 is amended by revising paragraphs (a), (c), and (g) to read as follows:

§ 95.628 MedRadio Transmitters

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(a) *Frequency monitoring.* Except as provided in (b) below, all MedRadio programmer/control transmitters operating in the 401-406 MHz, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter operating in the 401-406 MHz band initiates a MedRadio communications session, the following access criteria must be met:

* * * * *

(c) *Operating frequencies.* MedRadio stations authorized under this Part may operate on frequencies in the 401-406 MHz, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands as follows, provided that the out-of-band emissions are attenuated in accordance with § 95.635:

* * * * *

(5) MedRadio stations associated with MMN devices may operate on any of the frequencies in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, subject to the following channel plan:

Lower Channel Edge (MHz)	Center Channel Frequency (MHz)	Upper Channel Edge (MHz)
413.919	416.405	418.891
426.349	428.835	431.321
438.779	441.265	443.751
451.209	453.695	456.181

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(g) *Measurement procedures.*

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(3) Radiated emissions and EIRP limit measurements limit may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 1 milliwatt, 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 115.1, 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 57.55, 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Power measurements for transmissions by stations authorized under this section may be made either in accordance with a Commission-approved peak power technique, or the following. Peak transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms-equivalent voltage. The measurement results shall be properly adjusted for any instrument limitations, such as detector response times, limited resolution bandwidth capability when compared to the emission bandwidth, sensitivity, etc., so as to obtain a true peak measurement for the emission in question over the full bandwidth of the channel.

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(ii) For MedRadio transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, measurements are made over a bandwidth of 1 MHz or the 20 dB emission bandwidth of the device, whichever is less. A resolution bandwidth less than the measurement bandwidth can be used, provided that the measured power is integrated to show total power over the measurement bandwidth. If the resolution bandwidth is approximately equal to the measurement bandwidth, and much less than the emission bandwidth of the equipment under test, the measured results shall be corrected to account for any difference between the resolution bandwidth of the test instrument and its actual noise bandwidth.

3. Section 95.633 is amended by revising paragraph (e) to read as follows:

§ 95.633 Emission bandwidth.

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(e) For transmitters in the MedRadio Service:

(1) For stations operating in 402-405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401-401.85 MHz or 405-406 MHz, the maximum authorized emission bandwidth is 100 kHz, and stations operating in 401.85-402 MHz, the maximum authorized emission bandwidth is 150 kHz. For stations operating in 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz, the maximum authorized emission bandwidth is 5 MHz.

4. Section 95.635 is amended by revising paragraph (d) to read as follows:

§ 95.635 Unwanted radiation.

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(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following: (Subparagraphs 1 through 5 pertain to MedRadio transmitters operating in the 402-405 MHz band; subparagraphs 6 through 10 pertain to MedRadio transmitters operating in the 401-402 MHz or 405-406 MHz bands; subparagraphs 11 through 15 pertain to MedRadio transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands)

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(11) Emissions from a MedRadio transmitter more than 2.5 MHz outside of the 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz band shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength ($\mu\text{V/m}$)	Measurement distance (m)
30-88	100	3
88-216	150	3
216-960	200	3
960 and above	500	3

Note – At band edges, the tighter limit applies.

(12) The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. See also § 95.605.

(13) The emissions from a MedRadio transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(14) Emissions within the 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz band more than 2.5 MHz away from the center frequency of the spectrum the transmission is intended to occupy will be attenuated below the transmitter output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(15) Emissions 2.5 MHz or less above or below the 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz band will be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

5. Section 95.639 is amended by revising paragraph (f) to read as follows:

§ 95.639 Maximum transmitter power.

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(f) In the MedRadio Service for transmitters that are not excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the maximum radiated power in any 300 kHz bandwidth by MedRadio transmitters operating at 402-405 MHz, or in any 100 kHz bandwidth by MedRadio transmitters operating at 401-402 MHz or 405-406 MHz shall not exceed 25 microwatts EIRP. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 402-405 MHz shall not exceed 100 nanowatts EIRP confined to a maximum total emission bandwidth of 300 kHz centered at 403.65 MHz. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 401-401.85 MHz or 405-406 MHz shall not exceed 250 nanowatts EIRP in any 100 kHz bandwidth and in 401.85-402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§ 95.633(e). For MedRadio transmitters operating in 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or $10 \log B - 6.866$ dBm, where B is the 20 dB emission bandwidth in MHz; and the peak power spectral density shall not exceed 800 microwatts per MHz in any 1 MHz band. The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance with these EIRP limits may be determined as set forth in § 95.628(g).

6. Appendix 1 to Subpart E of Part 95—Glossary of Terms is amended by adding the definitions of “contention-based protocol,” “Medical Micropower Network,” “MMN control transmitter,” and “MMN transmitter,” in alphabetical order, to read as follows:

APPENDIX 1 TO SUBPART E OF PART 95—GLOSSARY OF TERMS

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Contention-based protocol. A protocol that allows multiple users to share the same spectrum by defining the events that must occur when two or more transmitters attempt to simultaneously access the same channel and establishing rules by which a transmitter provides reasonable opportunities for other transmitters to operate. Such a protocol may consist of procedures for initiating new transmissions, procedures for determining the state of the channel (available or unavailable), and procedures for managing retransmissions in the event of a busy channel.

Medical Micropower Network (MMN). An ultra-low power wideband network consisting of an MMN control transmitter and one or more MMN transmitters, including at least one medical implant transmitter, 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.

MMN control transmitter. An MMN transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver, or for triggering a transmitter, connected to a medical implant device used in the same MMN system.

MMNS transmitter. A transmitter authorized to operate as part of an MMN system.

7. Section 95.1209 is amended by revising paragraph (e) to read as follows:

§ 95.1209 Permissible communications.

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(e) MedRadio programmer/control transmitters operating in the 401-406 MHz band may not be used to relay information to a receiver that is not included with a medical implant or medical body-worn device. For MedRadio operation in the 401-406 MHz band, wireless retransmission of information intended to be transmitted by a MedRadio programmer/control transmitter or information received from a medical implant or medical body-worn transmitter shall be performed using other radio services that operate in spectrum outside of the 401-406 MHz band.

8. Section 95.1211 is amended by revising paragraph (c) and adding paragraph (d) to read as follows:

§ 95.1211 Channel use policy.

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(c) MedRadio operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, or to other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands. MedRadio stations must accept any interference from stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, and from other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

(d) All MMNS stations must employ the same contention-based protocol.

9. Section 95.1215 is amended to read as follows:

§ 95.1215 Disclosure policies.

Manufacturers of MedRadio transmitters must include with each transmitting device the following statement: “This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in Part 95 of the FCC Rules). It must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services, or in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”

10. Section 95.1217 is amended by revising paragraph (a) to read as follows:

§ 95.1217 Labeling requirements.

(a) MedRadio programmer/control transmitters shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

“This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services, or in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept any interference received, including interference that may cause undesired operation.”

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.