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VIA ELECTRONIC FILING

Marlene H Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, DC 20554

Re: Notice of Ex Parte Presentation
WT Docket No. 10-119

Dear Ms. Dortch:

This is to note that on August 2, 2017, I met on behalf of Medtronic, Inc., with Scot Stone, Deputy Chief of the Mobility Division of the Wireless Telecommunications Bureau, and Tom Derenge, Chief Engineer of the Division, to discuss possible revisions to the recently adopted Part 95 Rules. Charles Farlow, Medtronic's Senior Program Director, Regulatory Affairs, Cardiac Rhythm and Heart Failure, and Philip Inglis, Medtronic's electromagnetic compatibility consultant, participated in the meeting by telephone. We discussed the Commission's stated goal that no substantive changes had been intended for the MedRadio regulations and reviewed a short list of new regulations that contained either typographic errors or changes that may be susceptible to interpretations that could be considered to effect substantive changes with respect to the current MedRadio rules. A copy of the analysis we discussed is attached.

Respectfully,

/s/ David E. Hilliard

David E. Hilliard
Counsel for Medtronic, Inc.

Attachment

cc: Scot Stone, Thomas Derenge (w/ attachment)

Proposed Editorial Changes to the Revised 401 – 406 MHz MedRadio Part 95 Rules

WT Docket No. 10-119

Principle: "Other than the reorganization of the rules to fit the new template, we make no substantive changes to the MedRadio Service,211 Low Power Radio Service, and Multi Use Radio Service." ¶ 81, Report and Order, FCC 17-57 (rel. July 14, 2017).

§ 95.303 Definitions.

The following terms and definitions apply only to the rules in this part.

Antenna. A device that converts radio frequency electrical energy from a transmitter to radiated electromagnetic energy.

Authorized bandwidth. For other than the 401-406 MHz MedRadio frequency band, t~~T~~he maximum permissible occupied bandwidth of an emission. For the 401-406 MedRadio frequency band, the maximum permissible bandwidth of an emission.

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Commented [1]: The second sentence of this definition is identical to language currently included in Appendix I to Subpart E of Part 95. This change is required because the measurement of "occupied bandwidth" is not required in the current MedRadio rules. Note, "occupied bandwidth" is a defined term in the new rules.

Subpart I – Medical Device Radio Communications Service

ADMINISTRATIVE RULES

§ 95.2501 Scope.

This subpart contains rules that apply only to the Medical Device Radio Communications (MedRadio) Service.

§ 95.2503 Definitions, MedRadio.

Medical implant transmitter. A MedRadio transmitter in which both the antenna and transmitter device are designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

Commented [2]: The replacement of "if" with "of" returns this definition to language currently included in Appendix I to Subpart E of Part 95. The use of "if" in the new rules appears to be a typographical error.

§ 95.2533 Prohibited MedRadio uses.

MedRadio Service transmitters must not be operated for uses other than those set forth in § 95.2531.

(a) Voice communications are prohibited in the MedRadio Service.

(b) MedRadio programmer/control transmitters may not be used to relay information in the 401–406 MHz band to a receiver that is not included with a medical implant or medical body-worn device. 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.

(c) MedRadio programmer/control transmitters and medical implant transmitters may not be used to relay information in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands to a receiver that is not a part of the same Medical Micropower Network (MMN). Wireless retransmission of information to a receiver that is not part of the same MMN must be performed using other radio services that operate in spectrum outside of the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands. Notwithstanding the above restrictions, a MedRadio programmer/control transmitter of an MMN may communicate with a MedRadio programmer/control transmitter of another MMN to coordinate transmissions, so as to avoid interference between the two MMNs.

(d) Medical body-worn transmitters may relay only information in the 2360–2400 MHz band to a MedRadio programmer/control transmitter or another medical body-worn transmitter device that is part of the same Medical Body Area Network (MBAN). A MedRadio programmer/control transmitter must not be used to relay information in the 2360–2400 MHz band to other MedRadio programmer/control transmitters. Wireless retransmission of all other information from an MBAN transmitter to a receiver that is not a part of the same MBAN shall be performed using other radio services that operate in spectrum outside of the 2360–2400 MHz band. Notwithstanding the above restriction, a MedRadio programmer/control transmitter in the 2360-2400 MHz band may communicate with another MedRadio programmer/control transmitter in the 2360-2400 MHz band to coordinate transmissions so as to avoid interference between the two MBANs.

(e) Except as provided in § 95.2559(b), no MedRadio implant or body-worn transmitter shall transmit except in response to (i) a transmission from a MedRadio programmer/control transmitter or (ii) a non-radio frequency actuation signal generated by a device external to the body with respect to which ~~device~~ the MedRadio implant or body-worn transmitter is used.

Commented [3]: The deletion of the second "device" returns the last portion of this section to language included in § 95.1209(b) of the current rules.

§ 95.2557 MedRadio duration of transmissions.

For the purpose of facilitating MedRadio system operation during a MedRadio communications session, the duration of transmissions is to be limited in accordance with this section.

(a) MedRadio transmitters may transmit in the 401–406 MHz band in accordance with the provisions of § 95.2559(a) for no more than 5 seconds without the communications of data.

(b) MedRadio transmitters may transmit in the 401–406 MHz band in accordance with the provisions of § 95.2559(b)(2) and § 95.2559(b)(3) for no more than 3.6 seconds in total within a one hour time period ~~without the communications of data~~.

(c) MedRadio transmitters may transmit in the 401–406 MHz band in accordance with the provisions of § 95.2559(b)(4) for no more than 360 milliseconds in total within a one hour time period ~~without the communications of data~~.

(d) MedRadio programmer/control transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands shall not transmit with a duty cycle greater than 3 percent.

Commented [4]: The deletion of "without the communications of data" returns this section to language included in current §95.1209(d). The current rule limit of 3.6 seconds applies to any type of transmission (with or without data). The phrase "without the communications of data" appears to have been added in an effort to be stylistically congruent with new § 95.2557(a). The deleted text is superfluous. A provision limiting transmissions without data is, however, appropriate with respect to §95.2557(a) as that provision relies on a Listen Before Talk protocol. The concern with the provisions in §95.2557(b) and (c) is that the text as released might erroneously be construed as implying no time limit on transmissions with data.

Commented [5]: See the preceding comment.

§ 95.2559 MedRadio channel access requirements.

To reduce interference and make the most effective use of the MedRadio frequency bands, MedRadio transmitter types must be designed to operate in accordance with the rules in this section.

(a) *Frequency monitoring in the 401–406 MHz band*. Except as provided in paragraph (b) below, all MedRadio programmer/control transmitters operating in the 401–406 MHz band 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 MedRadio communications session. Before the monitoring system of a programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:

(1) The monitoring system bandwidth, measured at its 20 dB down points, must be equal to or greater than the MedRadio emission bandwidth of the intended transmission.

(2) Within 5 seconds prior to initiating a MedRadio communications session, circuitry associated with a MedRadio programmer/control transmitter must monitor the channel or channels the system devices intend to occupy for a minimum of 10 milliseconds per channel.

(3) The monitoring threshold power level, $P_{MT,}$ in dBm, is calculated using the following formula.

$$P_{MT} = 10 \log B - 150 \text{ (dBm/Hz)} + G$$

where:

(i) B is the MedRadio emission bandwidth in Hertz of the MedRadio communications session transmitter having the widest emission; and,

(ii) G is the MedRadio programmer/control transmitter monitoring system antenna gain, in decibels, relative to the gain of an isotropic antenna (dBi).

(4) For the purposes of showing compliance with the above provisions, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.

(5) If no signal above the monitoring threshold power level is detected in a MedRadio channel, the MedRadio programmer/control transmitter may initiate on that channel a MedRadio communications session involving transmissions to and from a medical implant or medical body-worn device. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If no channel meeting the requirements in paragraphs (a)(3) and (a)(4) of this section is available, MedRadio transmitters that are capable of operating on multiple channels may transmit on the alternate channel accessible by the device with the lowest monitored ambient power level.

(6) When a channel is selected prior to a MedRadio communications session, it is permissible to select an alternate ~~authorized~~ channel for use if communications are interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:

Commented [6]: The deletion of "authorized" returns this section to language included in current §95.627(a)(5). The use of "authorized" in the new rules implies fixed channelization in the MedRadio frequency allocation, for which the 401-406 MedRadio rules do not provide.

(i) Before transmitting on the alternate channel, the channel must be monitored for a period of at least 10 milliseconds.

(ii) The detected power level during this 10 millisecond or greater monitoring period must be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

(iii) In the event that this alternate channel provision is not used by the MedRadio system, or if the criteria in sub-paragraphs (i) and (ii) above are not met, ~~any alternate authorized~~ a channel must be selected using the access criteria specified in paragraphs (a)(1) through (a)(5) of this section.

(7) Except as provided in paragraph (b) of this section, MedRadio transmitters that operate on a single channel and thus do not have the capability of operating on alternate channels may not transmit unless no signal on the single channel of operation exceeds the monitoring threshold power level.

(b) *Exceptions to frequency monitoring in the 401–406 MHz band.* MedRadio devices or communications sessions that meet any one of the following criteria are not required to be operated in accordance with the access rules set forth in paragraph (a) of this section:

(1) MedRadio communications sessions that are initiated by a medical implant event.

(2) MedRadio devices operating in either the 401–401.85 MHz or 405–406 MHz bands, provided that the transmit power is not greater than 250 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.1 %, based on the total transmission time during a one-hour interval, and a maximum of 100 transmissions per hour.

(3) MedRadio devices operating in the 401.85–402 MHz band, provided that the transmit power is not greater than 25 microwatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval, and a maximum of 100 transmissions per hour.

(4) MedRadio devices operating with a total emission bandwidth not exceeding 300 kHz, centered at 403.65 MHz, provided that the transmit power is not greater than 100 nanowatts EIRP and the duty cycle

for such transmissions does not exceed 0.01 %, based on the total transmission time during a one-hour interval and a maximum of 10 transmissions per hour.

(c) *Shared access*. The provisions of this section shall not be used to extend the range of spectrum occupied over space or time for the purpose of denying fair access to spectrum for other MedRadio systems.

(d) *Frequency monitoring in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands.* MedRadio programmer/control transmitters must incorporate a mechanism for monitoring the authorized bandwidth of the frequency band that the MedRadio transmitters intend to occupy. The monitoring system antenna shall be the same antenna used by the programmer/control transmitter for a communications session.

(1) The MedRadio programmer/control transmitter shall be capable of monitoring any occupied frequency band at least once every second and monitoring alternate frequency bands within two seconds prior to executing a change to an alternate frequency band.

(2) The MedRadio programmer/control transmitter shall move to another authorized frequency band within one second of detecting a persistent (*i.e.*, lasting more than 50 milliseconds) signal level greater than −60 dBm as received by a 0 dBi gain antenna in any 12.5 kHz bandwidth within the authorized bandwidth.

(3) The MedRadio programmer/control transmitter shall be capable of monitoring the authorized bandwidth of the occupied frequency band to determine whether either direction of the communications link is becoming degraded to the extent that communications is likely to be lost for more than 45 milliseconds. Upon making such a determination the MedRadio programmer/control transmitter shall move to another authorized frequency band.

(e) *System shutdown.* MedRadio transmitters shall incorporate a programmable means to implement a system shutdown process in the event of communication failure, on command from the MedRadio programmer/control transmitter, or when no authorized alternate frequency band is available. The shutdown process shall commence within 45 milliseconds after loss of the communication link or receipt of the shutdown command from the MedRadio programmer/control transmitter. This requirement does not apply to MedRadio operations in the 401-406 MHz band.

Commented [7]: The replacement of "any alternate authorized channel" with "a channel" returns this section to language included in current §95.627(a)(5)(iii). The use of "alternate authorized" implies 1) fixed channelization and 2) multiple alternate channels. Per new § 95.2559(a)(6), only one alternate channel is permitted. See also, current §95.627(a)(5).

(f) *Requirements for MBAN Networks.* A MedRadio programmer/control transmitter and its associated medical body-worn transmitters shall not commence operating in, and shall automatically cease operating in, the 2360–2390 MHz band if the programmer/control transmitter does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation. Medical body-worn transmitters shall cease operating in 2360–2390 MHz if they lose communication with their associated programmer/control transmitter. Additionally, a MedRadio programmer/control transmitter and its associated medical body-worn transmitters operating in the 2360–2390 MHz band shall comply with a control message that notifies the devices to limit transmissions to segments of the 2360–2390 MHz band or to cease operation in the band.

§ 95.2579 MedRadio unwanted emissions limits.

Unwanted emission field strength limits and attenuation requirements apply to each MedRadio transmitter type, as set forth in this section and part 2.

(a) *Field strength limits.* The field strengths of unwanted emissions from each MedRadio transmitter type, measured at a distance of 3 meters, must not exceed the field strength limits shown in the table in this paragraph for the indicated frequency ranges, if the frequencies of these emissions are:

(1) More than 250 kHz outside of the 402–405 MHz band (for devices designed to operate in the 402–405 MHz band);

(2) More than 100 kHz outside of either the 401–402 MHz or 405–406 MHz bands (for devices designed to operate in the 401–402 MHz or 405–406 MHz bands);

(3) In the 406.000–406.100 MHz band (for devices designed to operate in the 401–402 MHz or 405–406 MHz bands); or

(4) More than 2.5 MHz outside of the 413–419 MHz, 426–432 MHz, 438–444 MHz or 451–457 MHz bands (for devices designed to operate in these four bands).

(5) More than 2.5 MHz outside of the 2360–2400 MHz band (for devices designed to operate in the 2360–2400 MHz band).

Frequency Range (MHz)	Field strength (μV/m)
30-88……	100
88-216…….	150
216-960……	200
960 and above…….	500

Note to Table: At the boundaries between frequency ranges, the tighter limit (lower field strength) applies. Below 1 GHz, field strength is measured using a CISPR quasi-peak detector. Above 1 GHz, field strength is measured using an average detector with a minimum reference bandwidth of 1 MHz. *See also* part 2, subpart J of this chapter.

(b) *Harmonic emissions.* Radiated unwanted emissions from a MedRadio transmitter type must be measured to at least the tenth harmonic of the highest fundamental frequency emitted.

(c) *Attenuation requirements, 402–405 MHz.* For MedRadio transmitter types designed to operate in the 402-405 MHz band, unwanted emissions must be attenuated below the maximum permitted transmitter output power by at least:

(1) 20 dB, on any frequency within the 402–405 MHz band that is more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy~~occupied bandwidth~~;

(2) 20 dB, on any frequency between 401.750 MHz and 402.000 MHz, and on any frequency between 405 MHz and 405.250 MHz.

(d) *Attenuation requirements, 401–402 MHz, 405–406 MHz.* For MedRadio transmitter types designed to operate in the 401–402 MHz band or 405–406 MHz band, the power of unwanted emissions must be attenuated below the maximum permitted transmitter output power by at least:

(1) 20 dB, on any frequency within the 401–401.85 MHz or 405–406 MHz bands that is:

(i) More than 75 kHz away from the center frequency of the spectrum the transmission is intended to occupy~~occupied bandwidth~~ if the MedRadio transmitter type is operating on a frequency between 401.85 and 402 MHz; or,

Commented [8]: The measurement of "occupied bandwidth" is not defined in current MedRadio rules. The replacement text returns this section to language included in current rules §95.635(d)(5).

Commented [9]: The insertion of "maximum permitted" returns this section to language included in current rules §95.635(d)(5). This correction is required to accommodate technically-feasible transmitter architectures.

Commented [10]: The measurement of "occupied bandwidth" is not defined in current MedRadio rules. The replacement text returns this section to language included in current rules §95.635(d)(5).

(ii) More than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupyoccupied bandwidth and 100 kHz or less below 401 MHz or above 406 MHz.

(2) 20 dB, on any frequency between 400.900 MHz and 401.000 MHz, and on any frequency between 406.000 MHz and 406.100 MHz.

(e) *Attenuation requirements, 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz.* For MedRadio transmitter types designed to operate in the 413–419 MHz, 426–432 MHz, 438–444 MHz and 451–457 MHz bands: In the first 2.5 megahertz above or below any of the frequency bands authorized for Medical Micropower Network operation, the EIRP of any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP within any 1 megahertz bandwidth of the fundamental emission.

(f) *Attenuation requirements, 2360–2400 MHz.* For MedRadio transmitter types designed to operate in the 2360–2400 MHz band: In the first 2.5 megahertz above or below any of the frequency bands authorized for MBAN operation, the EIRP of any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP within any 1 megahertz bandwidth of the fundamental emission.

(g) *Measurements.* Compliance with the limits in paragraphs (c), (d) and (e) of this section is based on the use of measurement instrumentation using a peak detector function with an instrument resolutionreference bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

Commented [11]: The measurement of "occupied bandwidth" is not defined in current MedRadio rules. The replacement text returns this section to language included in current rules §95.635(d)(5).

Commented [12]: The replacement of reference" with "resolution" returns this section to language included in current rules §95.635(d)(8). This change is required for the rule to be accurate technically.