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November 12, 2009

**VIA ECFS**

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

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**Re: *Ex Parte* Notification - Investigation of the Spectrum Requirements  
for Advanced Medical Technologies – ET Docket No. 06-135  
Amendment of Parts 2 and 95 of the Commission’s Rules To Establish  
The Medical Data Service at 401-402 and 405-406 MHz – RM-11271**

Dear Secretary Dortch:

This letter provides notice of a meeting that occurred on November 10, 2009, between representatives of Medtronic, Inc., and members of the Commission’s Office of Engineering and Technology (“OET”) relating to the Petition for Reconsideration of Medtronic, filed in the above-referenced dockets on June 15, 2009. Medtronic was represented by Medtronic’s CRDM Senior Program Manager, Charles Farlow, Phillip Inglis of TRP, Inc., and the undersigned counsel to Medtronic. Representing OET were Julius Knapp, Alan Stillwell, Ira Keltz, Gary Thayer, Mark Settle, Jamison Prime, Bruce Romano, Geraldine Matise, and via video-conference from the OET Laboratory, Rashmi Doshi, Joe Dichoso, William Hurst, and Steve Jones.

Medtronic presented the material provided in the attachment to this letter, which the parties subsequently discussed.

Please do not hesitate to contact the undersigned if the Commission has any questions regarding this letter.

Sincerely,

*David E. Hilliard*

David E. Hilliard  
John W. Kuzin

Att.



November 12, 2009

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cc w/ Att. via e-mail:

Julius Knapp  
Bruce Romano  
Alan Stillwell  
Geraldine Matise  
Ira Keltz  
Gary Thayer

Mark Settle  
Jamison Prime  
Rashmi Doshi  
Joe Dichoso  
William Hurst  
Steve Jones



# **Petition for Reconsideration of Medtronic, Inc.**

**MedRadio Report and Order  
(ET Docket No. 06-135, RM-11271)**

Medtronic

Nov. 10, 2009

# Agenda

- Introduction
- Review of Petition for Reconsideration
- Summary

# Petition for Reconsideration<sup>1</sup>

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D.	The Commission Should Clarify The MedRadio Rules So That Single-Channel LBT Devices Wait to Transmit When the Monitoring Threshold is Exceeded. ....	9	Clarification of rules
E.	The FCC Should Clarify The Rules Detailing Certain Exceptions To The Frequency Monitoring Criteria. ....	11	Align rules with text of Order <sup>2</sup>
F.	The FCC Should Correct The Rule Detailing Permissible Communications For Devices That Operate Pursuant To Exceptions To The Frequency Monitoring Criteria. ....	12	Correction of rules

<sup>1</sup>Petition for Reconsideration of Medtronic Inc., ET Docket No. 06-135, RM-11271 (June 15, 2009)

<sup>2</sup>See *MedRadio Report and Order* at ¶58 and ¶60

# The FCC Should Continue to Permit Measurements of MedRadio Transmit Power on the Basis of Average Power.

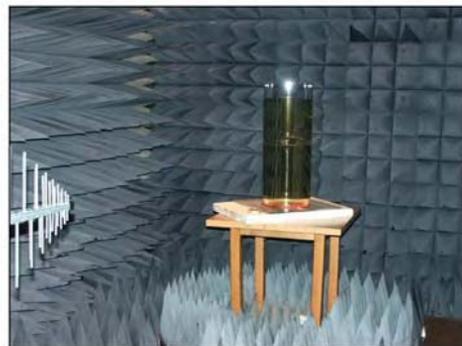
- Medtronic is requesting a return to the original MICS rules which allowed all technologies to radiate at the same power level when measured on the basis of average power
- This rule change was not raised in the *MedRadio NPRM* or by any party prior to the issuance of the *MedRadio Report and Order*
- In its Response on the Petition, Biotronik expressed a concern about increased interference in the band from “higher power levels,” but Medtronic is not proposing an increase in average power
  - Standard wireless interference analyses are based on average power
- The new rule limits innovation and will adversely impact products under development and emerging international standards (e.g., MedWiN proposal<sup>1</sup> for IEEE 802.15.6)
- St. Jude Medical supported Medtronic’s position in their Reply Comments

# The Human Torso Simulator and Test Technique in the Prior MICS Rules Should Be Expressly Permitted Under the MedRadio Rules.

- The FCC should include, as an option in the MedRadio rules, the torso simulator and test technique from the prior MICS rules, as modified in the January 10, 2008, *Ex Parte* Letter
- The human torso provisions of prior MICS rules are well understood and accepted by members of the implantable medical device industry



St. Jude Medical submission



Biotronik submission



Medtronic submission

# The Human Torso Simulator and Test Technique in the Prior MICS Rules Should Be Expressly Permitted Under the MedRadio Rules.

- Both Biotronik and St. Jude Medical support Medtronic's position
  - “St. Jude Medical agrees with Medtronic that reinstating the torso simulator and technique would be useful for device manufacturers that relied on the prior test configuration for developing equipment.”
  - “Biotronik agrees with Medtronic that the FCC should expressly allow the use of the human torso simulator and measurement technique that manufacturers have used for years under the prior MICS rules.”
- All FCC certified MICS band implantable devices have used the same torso simulator configuration
- The human torso simulator and test technique in the prior MICS rules have been recognized and adopted internationally (e.g., Japan, Korea, Canada, China, and European countries)

# The FCC Should Reconsider Its Decision to Reject Medtronic's Request to Relax the LBT Monitoring Threshold Level for Devices that Transmit with Less Power.

- Adjusting LBT threshold level (in proportion to radiated programmer/control transmit power) has been approved in the most recent ETSI MICS and MEDS standards
- Fundamental principle
  - A programmer/control transmitter operating with a lower radiated power level (e.g., 2.5 uW EIRP) has a smaller interference zone than one operating at maximum power (25 uW EIRP); it should not be required to monitor spectrum outside its interference zone
- Proposed rule allows
  - The monitoring system to function in applications where antenna gain, body absorption and/or proximity significantly affects system sensitivity relative to conventional medical implant programmer/control transmitters
  - A new class of low cost monitoring circuits in programmer/control transmitters with reduced EIRP, which facilitates reduced health care costs

# The Commission Should Clarify The MedRadio Rules So That Single-Channel LBT Devices Wait to Transmit When the Monitoring Threshold is Exceeded.

- 95.628(a) LBT operation
  - Medtronic requests that the FCC clarify that a single-channel MedRadio device that performs LBT may only transmit if the threshold level set forth in Rule Section 95.628(a) is not exceeded
  - Allowing devices to effectively transmit at will – which would be the case if a single channel LBT device could transmit even where the threshold is exceeded – will have a deleterious effect on the successful evolution of the MedRadio band
- 95.628(a)(4) operation
  - The Commission also should clarify that a MedRadio device that performs LBT and seeks to operate under the Least Interfered Channel (“LIC”) provisions in Rule Section 95.628(a)(4) must sense at least 9 channels if it operates in the core 402-405 MHz core band or at least 18 channels if it operates in the 401-402 and 405-406 MHz wing bands
  - Ensures successful spectrum sharing; aligns with approved ETSI MICS and MEDS standards

# The FCC Should Clarify The Rules Detailing Certain Exceptions To The Frequency Monitoring Criteria.

- MedRadio Rule Section 95.628(b) contains four exceptions, which allow communications without using the LBT access criteria defined in Section 95.628(a). The text of the MedRadio Report and Order limits the number of transmissions for these modes of operation to 10 or 100 discrete transmissions as specified,<sup>27</sup> but these restrictions were not added to the rules:

<sup>27</sup> See *MedRadio Report and Order* at ¶ 58 (permitting operation of devices centered at 403.65 MHz with a total emission bandwidth not exceeding 300 kilohertz, a maximum EIRP of 100 nW “and with maximum duty-cycle and transmission session limits of 0.01% **and ten per hour**”) (emphasis added); *id.* at ¶ 60 (“devices using non-LBT spectrum access methods in the new MedRadio wing bands at 401-402 and 405-406 MHz, we adopt power and duty cycle limits that match our proposals in the *MedRadio Notice*, namely a maximum EIRP of 250 nanowatts, together with a maximum duty cycle limit of 0.1% **and a maximum limit of 100 communication sessions per hour**”) (emphasis added). See also *id.* at ¶ 61 (“we will allow a maximum of 25 microwatts EIRP for devices using non-LBT spectrum access methods at 401.85-402 MHz.”).

# The FCC Should Clarify The Rules Detailing Certain Exceptions To The Frequency Monitoring Criteria.

- The proposed additions (to Rule Section 95.628(b)) aligns rules with text, prohibits excessive transmissions that could deny fair spectrum access, and achieves alignment with approved ETSI MICS and MEDS standards

(b) *Exceptions to frequency monitoring criteria.* MedRadio devices or communications sessions that meet any one of the following criteria are not required to use the access criteria set forth in paragraph (a) of this section:

...

(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.

# The FCC Should Correct The Rule Detailing Permissible Communications For Devices That Operate Pursuant To Exceptions To The Frequency Monitoring Criteria.

- Rule Section 95.1209(d) contains additional unnecessary language (which appears to be a typographical error)
- Transmissions without the carriage of data do not apply to systems that operate pursuant to exceptions to the frequency monitoring criteria, as set forth in Rule Section 95.628(b)(2), (3), & (4) – the intent of the 95.1209(d) for these type of systems is to specify a transmitter duty cycle limit
- Proposed correction:

**§ 95.1209 Permissible communications.**

...

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.628, MedRadio transmitters may transmit in accordance with the provisions of § 95.628(a) for no more than 5 seconds without the communications of data.; MedRadio transmitters may transmit in accordance with the provisions of § 95.628**(b)(2) & (b)(3)** for no more than 3.6 seconds in total within a one hour time period ~~without the communications of data~~; MedRadio transmitters may transmit in accordance with the provisions of § 95.628**(b)(2)** for no more than 360 milliseconds in total within a one hour time period ~~without the communications of data~~.

# Summary

- The changes outlined in Medtronic's Petition for Reconsideration:
  - Received broad industry support
  - Encourage innovation (e.g., increased data rates as proposed for IEEE 802.15.6)
  - Align FCC rules with approved international standards
  - Support the development of new, reduced cost, implantable / body worn medical devices and their associated peripherals
  - Ensure the fair sharing of MedRadio spectrum as implantable and body worn applications continue to increase
- Medtronic urges the FCC to adopt promptly all changes proposed within the Petition for Reconsideration