

**BEFORE THE  
FEDERAL COMMUNICATIONS COMMISSION  
WASHINGTON, DC 20554**

In the Matter of

Investigation of the Spectrum Requirements  
for Advanced Medical Technologies

Amendment of Parts 2 and 95 of the  
Commission's Rules To Establish The  
Medical Data Service at 401-402 and 405-  
406 MHz

ET Docket No. 06-135

RM-11271

**MEDTRONIC REPLY TO BIOTRONIK RESPONSE TO  
PETITION FOR RECONSIDERATION**

Medtronic, Inc., hereby replies to the response of Biotronik, Inc.,<sup>1</sup> to the Petition for Reconsideration of Medtronic<sup>2</sup> asking the Commission to reassess certain decisions and to clarify several new rules promulgated in the *MedRadio Report and Order*.<sup>3</sup> As the Petition explains, the items for which Medtronic is requesting reconsideration directly affect the continued viability of existing equipment and the successful development of next generation MedRadio equipment. With the exception of Biotronik's opposition to the first item in the Petition relating to the measurement of transmit power, Medtronic is pleased by Biotronik's support of the majority of remaining items in the Petition.

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<sup>1</sup> See Response of Biotronik, Inc. to Petition for Reconsideration of Medtronic Inc., ET Docket No. 06-135, RM-11271 (Aug. 11, 2009) ("Biotronik Response").

<sup>2</sup> See Petition for Reconsideration of Medtronic Inc., ET Docket No. 06-135, RM-11271 (June 15, 2009) (the "Petition").

<sup>3</sup> See Investigation of the Spectrum Requirements for Advanced Medical Technologies, *Report and Order*, ET Docket 06-135, FCC 09-23 (Mar. 20, 2009) ("*MedRadio Report and Order*").

In particular, 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. Biotronik also agrees that the FCC should clarify rules governing the operation of devices that incorporate listen before transmit (“LBT”) technology to make them consistent with the text of the *MedRadio Report and Order*, that is: (i) MedRadio devices that support LBT but operate on a single channel may transmit on that channel only when the frequency monitoring threshold is not exceeded, and (ii) MedRadio devices that seek to operate under the Least Interfered Channel (“LIC”) provision must sense and be able to operate across the MedRadio core band or wing bands. Finally, Biotronik supports correcting new Rule Section 95.1209(d) to reflect accurately the text of the *MedRadio Report and Order*, as set forth in the Petition.

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

Medtronic asked the FCC to reconsider its decision to change the prior MICS rules by requiring that transmit power measurements be made solely via use of a “Commission-approved peak power technique” or other technique “so as to obtain a true peak measurement.”<sup>4</sup>

Medtronic identified problems with the rule change: (1) it may adversely affect the compliance of existing MICS equipment; (2) it will adversely affect the development and performance of next generation MedRadio equipment;<sup>5</sup> and (3) the change was not the subject of any notice and comment as required by the Administrative Procedure Act (“APA”),<sup>6</sup> and thus lacks record support and is arbitrary and capricious. *See American Medical Ass’n v. United States*, 887 F.2d

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<sup>4</sup> See 47 C.F.R. § 95.628(g)(3); see also 47 C.F.R. § 95.639(f).

<sup>5</sup> See Petition at 3.

<sup>6</sup> See 5 U.S.C. § 553(b).

760, 769 (7th Cir. 1989) (“rule will be invalidated if no notice was given of an issue addressed by the final rules”); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008)(quoting *WJG Tel Co., Inc. v. FCC*, 675 F.2d 386, 389 (D.C. Cir. 1982) (citations omitted)) (longstanding precedent instructs that “[n]otice is sufficient ‘if it affords interested parties a reasonable opportunity to participate in the rulemaking process,’ and if the parties have not been ‘deprived of the opportunity to present relevant information by lack of notice that the issue was there.’”). In this proceeding, no party was afforded any notice of the change to the prior MICS transmit power measurement rule.

Biotronik opposes Medtronic’s request on the grounds that it “may allow devices with 3-5 dB more power within the band.”<sup>7</sup> Biotronik may have misunderstood the issue. While Biotronik expresses a concern about increased interference in the band from “higher power levels,” Medtronic is not proposing that one technology be permitted to radiate at a higher power level than another technology, but that all technologies be permitted to radiate at the same power level when measured on the basis of average power, as was the case under the prior MICS rules. In fact, in deciding to implement an average power measurement in place of a peak power measurement, the FCC has stated that the average power measurement approach offers a “more realistic and appropriate technique” and a “more accurate measure of the interference potential” of digital modulation technologies.<sup>8</sup>

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<sup>7</sup> Biotronik Response at 5. Biotronik does not challenge Medtronic’s statement that the specific rule change was not raised in the *MedRadio NPRM* and was never raised by any party prior to the issuance of the *MedRadio Report and Order*.

<sup>8</sup> See Service Rules for the 698-746, 747-762 and 777-792 MHz Bands, *Report and Order and Further Notice of Proposed Rulemaking*, 22 FCC Rcd 8064, ¶ 105 (2007) (“Although the use of ‘average’ power will effectively result in an increase in 700 MHz Band power levels for non-constant envelope technologies, such as CDMA and WCDMA, the ‘average’ measurement approach is a more accurate measure of the interference potential for these technologies. We find that any effective increase in power that would result through the use of an ‘average’

Just like the torso simulator and measurement procedure issue discussed in subsection B below (which Biotronik supports), Medtronic is simply asking the FCC to reinstate a regulation that was part of the prior MICS rules and extend it to the entire MedRadio band. Indeed, the *MedRadio NPRM*<sup>9</sup> did not propose any changes to the prior MICS measurement procedure that permitted average power measurements.<sup>10</sup> And, not a single party proposed changing this measurement procedure during the formal comment round or subsequent *ex parte* comments. Nonetheless, the FCC modified the regulation by deleting Rule Section 95.639(f)(1), which permitted average power measurements, and adding new Rule Section 95.628(g)(3), which appears to require use of peak measurements exclusively.

The average power measurement technique under the prior MICS rules referenced ANSI C63.17-1998, which is a technology neutral measurement specification that permits any modulation type to be used so long as the transmit EIRP does not exceed the limit, in this case 25  $\mu$ W. Such an approach is consistent with current ETSI standards that permit the use of peak *or* average measurement procedures.<sup>11</sup>

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measurement approach will be modest, and in any event will be outweighed by the benefit of measuring today's technologies using a more realistic and appropriate technique.”).

<sup>9</sup> See Investigation of the Spectrum Requirements for Advanced Medical Technologies, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, ET Docket 06-135, FCC 06-103 (July 18, 2006) (“*MedRadio NPRM*”).

<sup>10</sup> See 47 C.F.R. § 95.639(f)(1) (2008). The MEDS Petition for Rulemaking, which led to the *MedRadio NPRM*, proposed the same measurement procedure. See Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Data Service at 401-402 MHz and 405-406 MHz, Petition for Rulemaking, filed by Medtronic, Inc. (July 15, 2005), FCC Public Notice (rel. Aug. 24, 2005) RM-11271 (“MEDS Petition for Rulemaking”).

The MedRadio service is licensed by rule, see 47 C.F.R. § 95.1201, and the use of average power measurements is consistent with how the FCC treats other licensed services. See FCC OET Knowledge Database Entry 442401, indicating that the FCC Laboratory uses a measurement technique for licensed services based upon average power.

<sup>11</sup> See ETSI EN 301 839-1 V1.2.1 (2007-04) European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices

Under the measurement rule promulgated in the *MedRadio Report and Order*, device designs using advanced modulation techniques with a peak-to-average ratio of up to 5 dB will be restricted to between one-half to one-quarter of the power permitted for technologies with essentially constant modulation envelopes, such as (“FSK”).<sup>12</sup> Thus, by not allowing measurements to be made on the basis of average power, the FCC is restricting device flexibility and implementing a technological barrier to advanced, spectrally-efficient modulation techniques that provide higher data rates.<sup>13</sup> Indeed, the new rule favors device implementations that use relatively constant modulation envelopes and inherently have a lower data rate capability.<sup>14</sup>

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(SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods, § 6.8; ETSI EN 302 537-1 V1.1.2 (2007-12) European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods, § 6.8.

<sup>12</sup> Although today’s MICS devices utilize modulation techniques, such as Frequency Shift-Keying (“FSK”), that have an essentially constant modulation envelope, manufacturers are looking to implement in next generation devices higher order modulation schemes, which by their nature have higher peak-to-average ratios. For example, IEEE’s draft MedWIN standard includes (non-constant modulation envelope)  $\pi/4$ -DQPSK modulation for operations at 402-405 MHz. See IEEE P802.15 Working Group for Wireless Personal Area Networks (WPANs) MedWiN Physical Layer Proposal (May 4, 2009) available at <https://mentor.ieee.org/802.15/dcn/09/15-09-0329-00-0006-medwin-physical-layer-proposal-documentation.pdf>. The FCC’s decision to no longer allow average power measurements will restrict unnecessarily the development of next generation MedRadio technology.

<sup>13</sup> Section 95.628 of the MedRadio rules requires an LBT threshold power level measurement based on the ambient energy over a 10 ms monitoring interval (*i.e.*, “average power” over the interval) before accessing spectrum. Because the LBT threshold is based appropriately on average power, *see* n.8 *supra*, constant modulation envelope systems (where peak and average power are nearly equal) would preclude operation on a given channel at a much greater distance than would non-constant modulation envelope systems that are relegated to less average power under the new rule. This disparity in distance also may lead the non-constant modulation system to receive increased interference from a constant modulation system because the latter’s LBT function may not detect the non-constant modulation system.

<sup>14</sup> Interference to digital systems is assessed by decreases in throughput (higher bit error rates) due to increases in the signal-to-noise ratio of one dB as referenced in EIA/TIA TSB 10-F for microwave link performance. The parameters for signal-to-noise ratio variations are in terms

Accordingly, the FCC should grant the petition for reconsideration to allow the use of an average power measurement technique to show compliance with the limit by reinstating the prior rule or by restoring the intent of the prior rule as set forth in the Petition.<sup>15</sup>

**B. Biotronik Supports Adding Back Into the Rules the Human Torso Simulator and Test Technique From the Prior MICS Rules.**

Biotronik supports Medtronic's request to reinstate the torso simulator, tissue material, and test technique permitted under the prior MICS rules.<sup>16</sup> Biotronik rightly points out that the continuity of allowing the same test procedure would streamline equipment approval for manufacturers like Medtronic and presumably, Biotronik, that have "put resources into developing ways to use this technique."<sup>17</sup> Indeed, including the torso simulator and test technique in the rules offers specific guidance to device manufacturers and lessens the burden on FCC staff to review and approve multiple test methods.

As with the power measurement issue discussed above, the FCC implemented a rule change that was not discussed in the *MedRadio NPRM* or proposed by any party during the formal comment period or in subsequent *ex parte* presentations. As such, the change appears to violate the APA's notice and comment mandate, lack record support, and be arbitrary and capricious.<sup>18</sup>

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of power. Thus, allowing measurements to be made on the basis of average power equalizes all technologies and their interference potential.

<sup>15</sup> See Petition at 4.

<sup>16</sup> See Biotronik Response at 5; Petition at 5. The new rule requires that measurements "be made in accordance with a Commission-approved human body simulator and test technique." See 47 C.F.R. § 95.629(g)(3)(i).

<sup>17</sup> Biotronik Response at 5. Biotronik appropriately explains that the new rule introduces uncertainty for companies that have used the prior test configuration in developing equipment.

<sup>18</sup> See n.6, *supra*.

In its January 10, 2008, *Ex Parte* Letter, Medtronic presented a minor modification to the MEDS measurement proposal for body-worn devices to align it with the approach set forth in the ETSI standard.<sup>19</sup> Biotronik agrees that consistency with ETSI standards is a worthwhile goal.<sup>20</sup> Accordingly, Medtronic respectfully requests that the FCC include 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.

**C. The FCC Should Incorporate Into The Rules Medtronic's Request to Relax the LBT Monitoring Threshold Level for Devices that Use Less Power.**

No party opposed Medtronic's request to incorporate into the MedRadio rules the monitoring threshold relaxation set forth in the January 10, 2008, *Ex Parte* Letter for body-worn devices acting in the capacity of programmer/controllers.<sup>21</sup> Medtronic explained that the change would permit the increase of the LBT threshold by 1 dB for every 1 dB that the EIRP of the monitoring system transmitter is below the maximum permitted level of 25  $\mu$ W EIRP.<sup>22</sup> The requested change makes sound spectrum management sense and would greatly facilitate the implementation of body-area networks in which the programmer/controller also is a body-worn device that communicates with other body-worn and implantable devices.

The FCC's rejection of Medtronic's request on the basis that there was "insufficient notice" and "little substantive basis in the record"<sup>23</sup> was improper for the reasons set forth in the Petition and reiterated here: (1) the proposal falls squarely within the scope of the *MedRadio*

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<sup>19</sup> See Medtronic *Ex Parte* Letter in ET Docket No. 06-135, RM-11271 (Jan. 10, 2008) ("January 10, 2008, *Ex Parte* Letter") attached as Appendix A to the Petition. The proposal in the Medtronic *Ex Parte* Letter had just been adopted by ETSI. See Petition at 6.

<sup>20</sup> See Biotronik Response at 5.

<sup>21</sup> See Petition at 7-9.

<sup>22</sup> See January 10, 2008, *Ex Parte* Letter (attached to the Petition).

<sup>23</sup> *MedRadio Report and Order* at ¶ 55 n.76.

*NPRM* given that the frequency monitoring threshold level is a core component of the MedRadio LBT rules; (2) the proposal provided a sound foundation for implementing the threshold level adjustment; and (3) the proposal was unchallenged, which is not surprising because it had industry support by virtue of its adoption by ETSI and subsequent Harmonization under the Radio and Telecommunications Terminal Equipment (“RTTE”) directive.<sup>24</sup>

Accordingly, the Commission should implement the threshold relaxation set forth in the January 10, 2008, *Ex Parte* Letter.

**D. Biotronik Agrees That The FCC Should Clarify The Rules So That:  
(1) Single-Channel LBT Devices Wait to Transmit When the Monitoring  
Threshold is Exceeded; and (2) LBT Devices That Operate Under The Least  
Interfered Channel Provision Monitor The Whole Band.**

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Biotronik supports Medtronic’s request that the FCC make clear that a single-channel MedRadio device that performs LBT may transmit only if the monitoring threshold level in Rule Section 95.628(a) is not exceeded.<sup>25</sup> Biotronik agrees that allowing a single-channel LBT device to transmit where the monitoring threshold power level is exceeded would write the LBT requirement right out of the rule.

Biotronik also agrees that the Commission 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.<sup>26</sup>

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<sup>24</sup> ETSI implemented the threshold level relaxation in a portion of the band prior to Medtronic’s submission of the January 10, 2008 *Ex Parte* Letter, and ETSI adopted it for the remainder of the band shortly thereafter.

<sup>25</sup> Biotronik Response at 4.

<sup>26</sup> This is consistent with the proposals set forth in Medtronic’s September 17, 2007, *Ex Parte* Letter in ET Docket No. 06-135 & RM-11271 and in its January 10, 2008, *Ex Parte* Letter. *See also* FCC Rule Section 95.628(b)(4).

As Biotronik correctly explains, “[t]his will ensure that these devices operate on channels with the lowest ambient power levels, thereby effectuating successful band sharing.”<sup>27</sup>

Effectively allowing devices to transmit at will, as would be the case if a single-channel LBT device could transmit when the threshold is exceeded, would have a deleterious effect on the successful growth of the MedRadio band. Accordingly, the requested clarifications – both of which Biotronik endorses – are essential to ensuring successful band sharing as MedRadio device use increases and evolves.

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

No party opposed Medtronic’s request to include in the text of the rules the limit on the number of transmissions per hour for devices operating under the exceptions to the frequency monitoring criteria so as to make the rules consistent with the text of the *MedRadio Report and Order*.<sup>28</sup> Therefore, the FCC should clarify the rules as requested in the Petition.

**F. Biotronik Agrees That The FCC Should Correct The Rule Detailing Permissible Communications For Devices Operating Under An Exception To The Frequency Monitoring Criteria.**

Finally, Biotronik supports Medtronic’s request that the FCC correct new Rule Section 95.1209(d) to prohibit non-LBT devices from transmitting without the communications of data.<sup>29</sup> Biotronik also agrees that the references in Section 95.1209(d) to the numbered subsections in Section 95.628(b) should be corrected as set out in the Petition. These changes “will ensure that the low power, low duty cycle, access method is properly used and that permissible

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<sup>27</sup> Biotronik Response at 4-5.

<sup>28</sup> See Petition at 11-12 (referencing ¶¶ 58-61 of the *MedRadio Report and Order*).

<sup>29</sup> See Biotronik Response at 3-4; Petition at 12-13.

communications are not compromised by the use of incorrect duty cycles.”<sup>30</sup> Thus, the requested corrections to new Rule Section 95.1209(d) should be implemented without delay.

**II. CONCLUSION**

For the reasons set forth in the Petition for Reconsideration and in this Reply, Medtronic respectfully requests that the FCC grant the Petition in its entirety.

Respectfully submitted,

MEDTRONIC, INC.

By: */s/ Robert L. Pettit*

Robert L. Pettit  
David E. Hilliard  
John W. Kuzin  
Wiley Rein LLP  
1776 K Street, NW  
Washington, DC 20006  
*Its Attorneys*

August 21, 2009

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<sup>30</sup> Biotronik Response at 3-4.

## Service List

On the date below, a copy of the foregoing Medtronic Reply to Biotronik's Response to the Petition for Reconsideration was filed in ET Docket No. 06-135 and RM-11271, and a copy was sent via electronic mail to the following individuals:

Julius Knapp  
Chief  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Julius.Knapp@fcc.gov](mailto:Julius.Knapp@fcc.gov)

Ira Keltz  
Deputy Chief  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Ira.Keltz@fcc.gov](mailto:Ira.Keltz@fcc.gov)

Geraldine Matise  
Chief - Policy and Rules Division  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Geraldine.Matise@fcc.gov](mailto:Geraldine.Matise@fcc.gov)

Gary Thayer  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Gary.Thayer@fcc.gov](mailto:Gary.Thayer@fcc.gov)

Ron Repasi  
Deputy Chief  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Ronald.Repasi@fcc.gov](mailto:Ronald.Repasi@fcc.gov)

Bruce Romano  
Associate Chief  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Bruce.Romano@fcc.gov](mailto:Bruce.Romano@fcc.gov)

Mark Settle  
Deputy Chief - Policy and Rules Division  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, S.W.  
Washington, DC 20554  
[Mark.Settle@fcc.gov](mailto:Mark.Settle@fcc.gov)

Henry Goldberg, Esq.  
Laura Stefani, Esq.  
Goldberg, Godles, Wiener & Wright  
1229 19<sup>th</sup> Street, NW  
Washington, DC 20036  
[hgoldberg@g2w2.com](mailto:hgoldberg@g2w2.com)  
[lstefani@g2w2.com](mailto:lstefani@g2w2.com)

August 21, 2009

*/s/ John W. Kuzin*

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John W. Kuzin