

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of)
)
Amendment of Parts 2 and 95 of the) ET Docket No. 06-135
Commission's Rules to Establish the)
Medical Data Service at 401-402 MHz) RM-11271
And 405-406 MHz)

**RESPONSE OF BIOTRONIK, INC. TO
PETITION FOR RECONSIDERATION OF MEDTRONIC, INC.**

Biotronik, Inc. ("Biotronik") hereby responds to the Petition for Reconsideration ("Petition") filed by Medtronic, Inc., in the above-captioned proceedings.¹

On March 20, 2009, the Federal Communication Commission ("FCC") created the new MedRadio service by allocating additional spectrum to the former Medical Implant Communications Service ("MICS") and providing for additional types of operations on the band.² Biotronik applauds the FCC for issuing the MedRadio Order, and, in particular, providing for non-LBT access within the core MICS band. These actions will usher in tremendous new benefits for patients and their medical care by promoting further innovations in wireless medical technology.

¹ *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, Petition for Reconsideration of Medtronic, Inc., ET Docket No. 06-135 and RM -11271 (filed June 15, 2009) ("Petition").*

² *Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Report and Order, 24 FCC Rcd 3474 (2009) ("MedRadio Order").*

Medtronic has petitioned the FCC to reassess and clarify some of the new MedRadio rules. Biotronik supports some of the proposed clarifications to the new MedRadio rules, but does not agree with all of the suggestions outlined in the Petition. It is Biotronik's position that:

- FCC should correct Section 95.1209 as detailed in the Petition to ensure that non-LBT devices operate as intended.
- The rules should ensure that single-channel LBT devices wait to transmit when the monitoring threshold is exceeded.
- The FCC should expressly permit the use of the human torso simulator and test technique allowed under the prior rules, which would be consistent with European standards.
- Transmit power measurements should be made on the basis of peak power and not average power,

INTRODUCTION

Biotronik has been an active participant in this proceeding. Biotronik is a pioneer in the development of RF enabled medical device implants, namely implantable pacemakers ("IPGs") and implantable cardioverter defibrillators ("ICDs") operating within the MICS frequency for over eight years worldwide. Biotronik's cardiac implant devices transmit operational, diagnostic and therapeutic information to healthcare professionals via the public switched telephone network, both wireline and wireless. Biotronik's remote monitoring technology allows diagnostic and trend data, and other medically valuable information, of cardiac patients to be transmitted from these implants at any time from almost anywhere in the United States. Previously, this type of data only could be collected infrequently during office visits by the implant patient to his or her physician once every six months or annually.

Biotronik has been operating under the terms of a waiver that allows its devices to transmit periodically without following the listen-before-transmit (“LBT”) protocol.³ Due to this waiver, Biotronik devices have been able to transmit periodic trend data, information that has proven to be very beneficial to physician caregivers.

On June 16, 2006, Biotronik filed a Petition for Rulemaking seeking establishment of single channel in the existing MICS band where non-LBT access would be permitted.⁴ The Commission incorporated Biotronik’s suggestion into the MedRadio rules, paving the way for Biotronik to continue its operations under an exception to the frequency monitoring criteria once the waiver expires.⁵

DISCUSSION

I. **Biotronik Supports Correction of Section 95.1209, As Set Forth in the Petition.**

Medtronic requests that the Commission make certain corrections to Section 95.1209.⁶ Medtronic suggests that the Commission remove certain text from Section 95.1209(d) to ensure that non-LBT devices do not transmit without communicating data.⁷ Additionally, Medtronic asks that the references to Section 95.628(b) be corrected to accurately reflect the text of the MedRadio Order.⁸

Biotronik supports these corrections, as outlined in the Petition. Making these changes will ensure that the low power, low duty cycle access method is properly used

³ See *In the Matter of Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Order, 19 FCC Rcd 4208 (2004) (“*Biotronik Waiver*”). The MedRadio Order extended this waiver until one year after the effective date of the final MedRadio rules. See *MedRadio Order* at ¶ 69.

⁴ *Petition for Rule Making*, Biotronik, Inc. (filed June 16, 2006).

⁵ *MedRadio Order* at ¶ 58.

⁶ 47 C.F.R. § 95.1209.

⁷ *Petition* at 12.

⁸ *Id.*

and that permissible communications are not compromised by the use of incorrect duty cycles.

II. The Commission Should Clarify that Single-Channel LBT Devices Must Wait to Transmit When the Monitoring Threshold is Exceeded.

Medtronic requests that the Commission make clear that single-channel devices that employ the LBT access criteria wait to transmit if the monitoring threshold power level is exceeded.⁹ Medtronic also seeks clarification that LBT devices seeking to operate under the Least Interfered Channel provisions of Section 95.628(a)(4) must sense at least 9 channels if operating in the core band and 18 channels if operating in the wing bands.¹⁰ Biotronik supports both requests for clarification.

The original MICS rules were crafted so that medical devices could transmit on any one of the available shared channels, and a LBT requirement was put in place to ensure effective channel sharing. While certain devices have, and will continue to, access the band without using LBT requirement, these devices have sufficiently low transmit power and duty cycle so that other devices seeking to share the channel could do so. In the instance when a device is designed to operate only on one channel, however, and that device is LBT, *e.g.*, not limited in power level and duty cycle, that creates a concern of whether that one channel would be available to share with other devices. To ensure effective channel sharing in the spirit of the rules, the FCC should provide that single-channel devices using the LBT access method must wait to transmit if the channel on which they operate is occupied.

As well, the Commission must clarify that devices using the Least Interfered Channel provisions must monitor all relevant channels. This will ensure that these devices operate on channels with the lowest ambient power levels, thereby effectuating

⁹ *Petition* at 9.

¹⁰ *Petition* at 9-10.

successful band sharing. Biotronik believes that it is both the spirit and intent of the rules for the Commission to require that the LIC provisions be used only when the minimum number of channels are sensed.

III. The Human Torso Simulator and Test Technique of the MICS Rules Should be Permitted Expressly.

Biotronik supports reinstatement of the torso simulator, tissue material, and test technique rules previously allowed for making RF measurements on implantable medical devices.¹¹ Former Section 95.639(f)(2)(i) provided for specific human torso measurement techniques for implantable transmitters.¹² Maintaining this test procedure would be useful for device manufacturers that have put resources into developing ways to use this technique. Furthermore, expressly allowing use of this human torso simulator is consistent with European standards, which provide that active medical implants be tested on it.¹³

IV. The Use of Peak Power Rather Than Average Power Should be Retained.

Finally, the FCC should reject Medtronic's proposed changes to Section 95.628(g)(3)¹⁴ and retain the rule as drafted. Use of average power (as contrasted with peak power) as a measurement of transmit power may allow devices with 3-5 dB more power within the band.¹⁵ These higher power levels would have the effect of increasing possible interference within the band. Accordingly, Biotronik believes all manufacturers should adhere to a common power limit, measured in a standard manner (using a peak power detector per the new MedRadio rules).

¹¹ See *Petition* at 5.

¹² 47 C.F.R. § 95.639(f)(1)(i) (2008).

¹³ See Section 8.3.1.1. and Annex A, ETSI EN 301 839-1 v.1.2.1 (2007-07).

¹⁴ 47 C.F.R. § 95.639(g)(3).

¹⁵ See *Petition* at 5 (stating that the use of average power would cause certain devices to use 3-5 dB less power than under the prior MICS rules).

CONCLUSION

For the reasons stated herein, Biotronik requests that the Commission correct Section 95.1209, as detailed in the Petition. Biotronik also believes that clarification is needed to assure that single-channel non-LBT devices wait to transmit whenever the monitoring threshold is exceeded, and that the Least Interfered Channel provisions are clarified. As well, Biotronik supports specific reinstatement of the human torso simulator, tissue material, and test technique rules previously allowed. Finally, Biotronik requests that the Commission retain the peak power measurement requirement of Section 95.628(g)(3).

Respectfully submitted,
BIOTRONIK, INC.



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August 11, 2009