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By Electronic Filing

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

Re: ET Docket Nos. 06-135 & 05-213 and RM-11271
Ex Parte Presentation

Dear Ms. Dortch:

At the risk of extending an already protracted debate, Biotronik is compelled to correct the record following the most recent Medtronic *ex parte* filed with regard to the above-referenced proceedings.[1]

Statements Regarding ETSI Regulations

First, Medtronic's assertion that, "*… the trend [of regulatory agencies] has been LBT only or LBT and LP-LDC,*"[2] does not accurately describe the ETSI

[1] *Letter from David E. Hilliard to Marlene Dortch, Secretary, Federal Communications Commission*, (Nov. 1, 2007) ("Medtronic Ex Parte").
[2] *Id*. at 5.

regulatory scheme. The ETSI regulations, which Medtronic cites but does not quote, state:

> *It is mandatory that the manufacturer declares a spectrum access method. At least one of the following methods shall be chosen. A manufacturer may choose to implement both methods in his equipment, however, he may operate using both access methods if the total emission bandwidth does not exceed 300 kHz.*
>
> - *LBT/AFA [Listen Before Talk/Adaptive Frequency Agility] requirements for the monitoring system are specified in EN 301 839-1 [3], clause 10...*
> - *LP/LDC [Low Power/Low Duty Cycle] requirements are specified in EN 301 839-1 [3], clauses 8.3.2 and 8.6.3...* [3]

In other words, the ETSI regulations explicitly allow the low power, low duty cycle ("LP-LDC") access method requested by Biotronik in this proceeding.[4]

Similarly, Medtronic asserts: "*Biotronik's proposed use of the 403.5 to 403.8 MHz 'channel' as a beacon channel should be rejected because it [sic] contrary to the terms of the FCC's waiver and the European standard.*"[5] Medtronic is incorrect as to both assertions. Regarding the FCC waiver, there is nothing in the provisions of the waiver that would prohibit the use of LP-LDC as a beacon channel. As for the ETSI standards, those specifically permit a beacon channel. The ETSI Technical Report that explains the use of LP-LDC in the MICS band allows for the use of a beacon channel, which ETSI calls the Simplified Access Method. Specifically, the Report states that:

> *For some applications such as e.g. Home Monitoring this channel access method represents several advantages in relation to LBT:*
>
> - *Simplified access method.*
> - *Reduced timing synchronization requirements.*

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[3] ETSI EN 301 839-2 V1.2.1, § 4.2.8 Spectrum Access (2007-04).
[4] *See Letter from Henry Goldberg, Attorney for Biotronik, Inc., to Marlene Dortch, Secretary, Federal Communications Commission*, Attachment A (May 23, 2007) ("Biotronik Presentation") (discussing proposed LP-LDC access method).
[5] Medtronic Ex Parte at 6.

- *Extended battery life.*
- *Allows unidirectional transmission.*

> *Allowing the use of low duty cycle as an additional interference mitigation technique will allow medical device manufacturers to make use of these advantages.*[6]

The report defines Simplified Access Method as follows:

> *In such an implant-initiated transmission, the implant sends a short access request on the allowed access channel. The external patient device gets the access request and responds with what is essentially a LBT session; it scans channels and replies on the least interfered channel. The implant scans all channels, searching for this access response, and the telemetry session ensues.*[7]

This is precisely the function of the beacon channel Biotronik has urged the Commission to permit.

Statements Regarding Interference Potential

Medtronic attempts to obfuscate the record with regard to the interference potential of Biotronik's LP-LDC proposal by such statements as: "*Biotronik has acknowledged its devices will cause interference to LBT systems*" and "*Biotronik calculates a probability of collision between n = 1 LP-LDC transmissions and a single 100 ms LBT packet, which is unrepresentative of the real world.*"[8] Clearly, the potential for interference exists in any RF communication system. The relevant question is whether a specific level of interference is acceptable.

Biotronik has performed detailed simulations and analyses of interference using reported data and open-source tools, and has submitted them to peer-reviewed forums and has filed them in this proceeding.[9] No party has submitted any analysis that contradicts Biotronik's conclusion that LP-LDC would introduce an extremely low probability of interference and that, in any event, such interference would cause no harm. Medtronic presents the extreme case of

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[6] ETSI TR 102 434 V1.1.1, § 4.2.4 Spectrum Requirements and Justification (2005-06).
[7] *Id*.
[8] Medtronic Ex Parte at 4 and 6.
[9] IEEE Engineering in Medicine and Biology Conference, August 2007, Lyon, France. *See Letter from Henry Goldberg, Attorney for Biotronik, Inc., to Marlene Dortch, Secretary, Federal Communications Commission*, Attachment A (May 23, 2007) ("Biotronik Presentation").

an implant with up to two hours of real time electrogram transmission. Yet even in this situation, using Biotronik's interference probability analysis, fewer than 2 packets would be interfered with over a two hour session, which would not result in any harm because of other mitigation techniques inherent in any RF communication system.[10] As detailed in Biotronik's study,[11] this level of interference is several orders of magnitude less than interference caused by other LBT systems, and Medtronic has expressed confidence that LBT systems can use upper layer protocol methods to overcome even this level of interference.[12]

With regard to Biotronik's use of a certain Packet Error Ratio (PER) length (assumed 100 milliseconds packet length), the conclusion of Biotronik's analysis would be the same for any reasonable assumption of packet length. Specifically, the probability of interference for any reasonable packet length would remain extremely low and would not result in any harm.

Unnecessary Push for Device Power Consumption

Finally, Medtronic claims that, "[i]*n fact, the clear channel assessment portion of the MICS LBT protocol has limited impact on implant power consumption because it is conducted by the external MICS programmer/controller, not the implant.*"[13] This assertion fails to recognize the operations the implant undertakes to engage in a listen before talk ("LBT") session.

As shown in previous filings with the Commission,[14] in order to establish a communications session the implant must also scan all ten MICS channels to determine which channel the external programmer/controller has chosen. It is this process which draws current from the implant, limiting device longevity. Furthermore, this process clutters the MICS band with repeated transmissions from the external device while the search continues until the session is established. Thus, the use of LP-LDC, as described in previous Biotronik filings,

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[10] One relatively simple mitigation technique, for example, is retransmission. In the event that one or even 2 packets are interfered with over the course of two hours, a system could easily retransmit those packets without any impact on patient safety or overall system performance.
[11] Brian Sutton et al., *Probability of Interference between LP-LDC and LBT MICS Implants in a Medical Care Facility*, Proceedings of the 29th Annual International Conference of the IEEE EMBS, 6721-6725 (Aug. 23-26, 2007) (attached in Biotronik's ex parte filing dated Sept. 7, 2007).
[12] Medtronic Ex Parte at n.2.
[13] Medtronic Ex Parte at 5.
[14] *See* Biotronik Ex Parte of Sept. 25, 2006.

as a beacon channel, reduces the current drain of the implant and eliminates unneeded transmissions from the external programmer/controller.

Accordingly, Biotronik strongly urges the Commission to follow the lead of ETSI and allow a second access method, LP-LDC, within the MICS Band.

Please direct any questions to the undersigned.

Sincerely,

Henry Goldberg
Attorney for Biotronik, Inc.

cc: Julius Knapp
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