

**Before the
Federal Communications Commission
Washington, DC 20554**

In the Matter of

Biotronik, Inc.

Request for Waiver of the Frequency
Monitoring Requirements of the Medical
Implant Communications Service Rules

ET Docket No. 03-92

REPLY COMMENTS OF MEDTRONIC INC.

Medtronic Inc. (“Medtronic”) respectfully submits these reply comments in opposition to the Request for Waiver of the frequency monitoring requirements of the Medical Implant Communications Service (“MICS”) rules filed by Biotronik, Inc. (“Biotronik”).¹

The Comments of Biotronik² filed in support of its Request further confirm the points Medtronic made in its June 11, 2003, Opposition.³ Specifically, there is no compelling need to grant the Waiver Request, as there is alternative spectrum and existing regulations that can support Biotronik’s RF application. Upholding the forward-looking MICS rules requiring

¹ See Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92, filed Mar. 27, 2003 (hereinafter “Request for Waiver” or “Request”).

² See Comments of Biotronik, Inc., Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92, filed June 11, 2003 (“Biotronik Comments”).

³ See Opposition of Medtronic, Inc., Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92, filed June 11, 2003 (“Opposition”).

medical devices to listen before transmitting (“LBT”) best serves the public interest.⁴ It also addresses fully the interference concerns of NTIA, whose letter confirms that Biotronik’s fixed-frequency transmit-only devices will be susceptible to interference from primary METAIDS users.⁵

In addition, the Request for Waiver should not be granted where the company continues to flout the Commission’s direct orders and consistent rules. Finally, Biotronik fails to satisfy the legal burden necessary for a waiver of Commission rules, especially self-regulating rules that implement wise spectrum policy.

I. NTIA’S LETTER CONFIRMS THAT THE INTERFERENCE THREAT FROM METAIDS TO BIOTRONIK DEVICES IS “VERY REAL” AND THAT THE HOME FOR BIOTRONIK-LIKE DEVICES IS OUTSIDE THE MICS BAND.

Biotronik’s Request for Waiver states that its non-compliant “cardiac medical implant devices represent no risk of interference to other MICS users or to primary users of the 402-405 MHz band [and] are not susceptible to interference that may be caused by such users.”⁶

Biotronik’s Comments add that any interference concerns of NTIA are “unfounded.”⁷ To support these statements, Biotronik cites a few standards used by the FDA for electromagnetic

⁴ Biotronik explains in a footnote to its Comments that it could not describe the characteristics of its future devices. Biotronik Comments at 3 n.9. Nevertheless, Biotronik wants a waiver issued now to cover such future devices. This confirms Medtronic’s fear that grant of the instant Waiver Request will open the floodgates for additional and likely higher-powered and more spectrum intensive transmit-only 402-405 MHz products.

⁵ See Letter from Fred Wentland, NTIA to Edmond Thomas, FCC, Re: Biotronik Inc. Request for Waiver, dated May 22, 2003 (“NTIA Letter”) (emphasis added). Notably, NTIA does not address the threat of interference from Biotronik-like implants to MICS-compliant devices – a concern that must weigh into the FCC’s calculus, however, as MICS devices will operate under the auspices of FCC rules.

⁶ Request for Waiver at 5.

⁷ Biotronik Comments at 2.

compatibility review and claims that tests to these standards verify that the Biotronik devices are “immune to all sources of electronic noise”⁸ when, in reality, the standards bear no relation to the susceptibility of Biotronik’s transmissions to other interfering signals within the 402-405 MHz MICS band.⁹

The MICS rules, the European standards, and the International Telecommunications Union (“ITU”) Recommendation are each predicated on spectrum studies that demonstrate that interference to MICS devices from primary METAIDS and other MICS users will occur, and for that reason MICS devices were required to implement LBT to avoid interference from and to other spectrum users.¹⁰ In fact, in promulgating the MICS regulations, the FCC stated:

We believe that the adopted rules [requiring LBT] will allow use of newly-developed, life-saving medical technology without harming other users of the frequency band. ... We believe that these rules will ensure

⁸ Request for Waiver at 7 n.18.

⁹ The FDA standards cited by Biotronik explicitly exempt the receipt of data by Biotronik’s RF receiver system while in the presence of ambient signals at 402-405 MHz. *See, e.g.*, Section 36.202 of IEC 60601-1-2 (2d ed.) at ¶ 36.202.3(4) (“Equipment and systems that intentionally receive RF electromagnetic energy for the purpose of their operation are exempt from the ESSENTIAL PERFORMANCE requirements in 36.202.1 j in the EXCLUSION BAND.”). Paragraph 2.211 defines EXCLUSION BAND as the “frequency band for intentional receivers of RF electromagnetic energy that extends from –5% to +5% of the frequency, or frequency band, of reception for frequencies of reception greater than or equal to 80 MHz.”

The band from 383 MHz to 423 MHz, which includes the MICS band, is excluded from the testing for purposes of meeting the standard’s ESSENTIAL PERFORMANCE criteria. Accordingly, the standard exempts from consideration the medical system’s transmission and reception of data while in the presence of ambient signals when determining if the ESSENTIAL PERFORMANCE requirements are met.

¹⁰ Opposition at 20-23.

that neither Metatids nor MICS operations will experience any interference from sharing the 402-405 MHz band.¹¹

Confirming Medtronic's position, NTIA's recent letter responding to the Request for Waiver states unequivocally that the potential for interference from METAIDS devices (*i.e.*, radiosondes) to Biotronik's devices is "very real."¹² NTIA explains:

Radiosondes launches and landings can occur in many parts of the United States on a regular basis. These are operated by the National Weather Service, Department of Defense and others. The radiosondes may transmit for a long period of time, possibly exceeding a few hours. Considering the deployment and operational characteristics of radiosondes ... it is very probable that Biotronik's devices operating within [a] fairly large geographic area around these launch sites will receive interference.¹³

In view of these interference concerns, NTIA stipulated a number of conditions to be imposed should the Commission decide to grant a limited waiver. Specifically, NTIA says that any Waiver should be "limited to the device characteristics (*i.e.*, peak power, periodic transmission duration, and transmissions per day) discussed in the [Request for Waiver]."¹⁴

Biotronik's Request states that peak power for the devices covered is 6.27 nanowatts, the transmission duration is 80 milliseconds for the Philos DR-t and 270 milliseconds for the Belos

¹¹ See *Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, Report and Order*, 14 FCC Rcd 21040 ¶¶ 15-16 (1999) ("1999 MICS R&O").

¹² NTIA Letter at 2. Remarkably – and in a snub to another federal agency – Biotronik claims it "has demonstrated that NTIA's [interference] concern is unfounded." Biotronik Comments at 2 (emphasis added).

¹³ *Id.*

¹⁴ *Id.*

VR-t and Belos DR-t, and each daily transmission¹⁵ is sent a total of seven times (to increase the likelihood of receipt). Clearly, any modification to these stated parameters would require re-evaluation by NTIA.¹⁶

NTIA also requires that medical professionals be informed that “interference from radiosondes is a very real possibility” and that any Waiver “acknowledge Biotronik’s acceptance

¹⁵ The frequency of transmissions for the Philos DR-t can be set in one-day increments from daily to once every 30 days. Thus, no more than one distinct message per day is sent. *See* Biotronik Inc., Petition for Reconsideration or Waiver, Biotronik Inc. Grant of Equipment Authorization for the Medical Implant Communications Service, FCC ID PG6BA0T, Ref. No. 1300F2, Apr. 8, 2002, (“Biotronik 2002 Petition for Waiver”) at 11.

Unfortunately, Biotronik’s recent Request for Waiver does not explicitly state that the current devices transmit no more than one message per day. Notwithstanding, the single daily transmission from the Philos DR-t unit was the basis for the FCC’s determination that the interference potential from the device was *de minimis*. The FCC noted that the devices transmit for “about one half second per day with typical transmissions in the early hours of the morning.” Request for Waiver at 6, n.16 *citing* OET Letter Order at 3. Transmissions that occur more frequently will undoubtedly require re-evaluation by the Commission and NTIA of the interference issues both from and to other users of the 402-405 MHz band. Accordingly, any waiver should, at a minimum, be conditioned upon a peak power limit, periodic transmission duration, and maximum number of transmissions per day.

¹⁶ Biotronik is disingenuous in stating that it has NTIA has “no objection to the grant of Biotronik’s waiver request.” Biotronik Comments at 3. In fact, NTIA’s support is explicitly conditioned on five (5) clearly delineated terms, and one of the primary conditions is that the waiver be limited to the same “device characteristics (i.e. peak power, periodic transmission duration, and transmissions per day) discussed in the [Request for Waiver].” NTIA Letter at 2.

This condition is not acceptable to Biotronik: “Obviously, Biotronik did not, and could not, describe the specific operating characteristics of such future devices in its waiver request.” Biotronik Comments at 3 n. 9. (Indeed, the company has the capability to readily modify its equipment to exceed the operating characteristics stated in its Waiver. *See* n.27, *infra*.) However, Biotronik has delegated its problem to the Commission to work out with NTIA. “The Commission, therefore, should work with NTIA to clarify this statement.” Biotronik Comments at 3 n. 9.

of this interference.”¹⁷ NTIA also specifies that any device operation be limited to “non-critical communications for which failure will not affect the health or safety of the patient.”¹⁸

None of these conditions are needed for MICS-compliant equipment, which – unlike the Biotronik implants – can operate around primary users via use of smart transceivers that implement LBT.¹⁹ Indeed, for that reason, MICS-compliant devices are uniquely suited to support life-critical applications.²⁰ Biotronik’s admittedly “non-compliant” and “non-life critical”²¹ periodic scheduled transmissions should, however, operate outside of the MICS band.

Medtronic has informed the Commission – and Biotronik – that there is alternative spectrum (*e.g.*, under Part 15 of the FCC’s rules) that can currently support the periodic scheduled transmission feature of Biotronik’s implants.²² NTIA’s requested conditions are effectively equivalent to the Commission’s rules governing Part 15 operations. Part 15 requires that:

Operation of an intentional ... radiator [*i.e.*, the Biotronik implant] is subject to the conditions that no harmful interference is caused and that interference must be accepted that may be caused by the operation of an authorized radio station, by another intentional or unintentional radiator,

¹⁷ NTIA Letter at 2-3.

¹⁸ *Id.* at 2.

¹⁹ *See* 47 C.F.R. §§ 95.628(a), 95.1209(b), and 95.1211(b) (2002). *See also* Opposition at 7-9.

²⁰ *See* Opposition at 10-12.

²¹ *See* Request for Waiver at 3; Biotronik Comments at 3.

²² *See* Opposition at 5-7. *See also* Medtronic Application for Review, Biotronik Inc. Grant of Equipment Authorization for the Medical Implant Communications Service, FCC ID PG6BA0T, Apr. 8, 2002, at 3 n.8.

by industrial, scientific and medical (ISM) equipment, or by an incidental radiator.²³

Indeed, Biotronik has designed a device that *operates in the presence of interference from other users* by sending multiple messages containing identical data and allegedly *avoids causing interference to other spectrum users* by way of power levels that are substantially less than the levels allowable under MICS. These are the hallmarks of Part 15 operation.

Thus, because there is alternative spectrum amenable to Biotronik's application, there is no compelling need to intermix non-compliant transmit-only devices in a limited 3 MHz frequency band intended to be shared internationally among many manufacturers providing smart, reliable MICS-compliant medical devices. Biotronik's devices, which do not perform LBT, are unable to avoid interference from other spectrum users and cannot reliably support life-critical applications.²⁴

Biotronik's Request for Waiver is essentially requesting a re-write of the MICS rules to allow such non-LBT operations and will stunt the usefulness and growth of next-generation wireless medical equipment. Accordingly, the Request should be denied.²⁵

²³ 47 C.F.R. § 15.5(b) (2002).

²⁴ They are also unable to avoid causing interference in the band to MICS-compliant users and other non-compliant transmit-only implants. In addition, the interference to Biotronik's device could be more severe in other countries where higher-powered emitters are present at 402 to 405 MHz. *See* Opposition at 12-13.

²⁵ If the operation proposed by Biotronik in its Request for Waiver is to be permitted in the MICS band, any such re-write of the rules should come only after a full notice and comment rulemaking proceeding. *See, e.g., ICBC Corp. v. FCC*, 716 F.2d 926, 929 (D.C. Cir. 1983).

II. IF BIOTRONIK'S DEVICES ARE BEING USED FOR LIFE CRITICAL OPERATIONS, AS THEIR DOCTOR'S ATTEST, THEY SHOULD BE REQUIRED TO COMPLY FULLY WITH THE MICS RULES.

While Biotronik asserts that its implants' periodic scheduled transmissions do not serve a "life-critical" function in the treatment of cardiac patients, the letters from its doctors tout the devices' "life-saving" applications.²⁶ An implanted medical device that provides such a critical function to doctors should be required to comply with the MICS rules to ensure that messages from implanted devices are received by the external equipment.

Biotronik's implanted devices have no way of knowing if the information they transmit is received. Also, to increase the probability of receipt, Biotronik's devices transmit each message seven (7) times a day.²⁷ Significantly, a recent Biotronik study confirms that over ten percent

²⁶ Biotronik also contradicts itself in saying that "to comply with the [FCC's February 2003 MICS] decision, [and turn off periodic transmissions,] Biotronik has to rewrite the implant device's firmware so as to disable to periodic transmission mode," which is "a complicated and time consuming process." Request for Waiver at 2 n.4. According to the Waiver Request, the lengthy rewrite process must be followed by a lengthy "validation" process and then a "six month" FDA approval process. In sum, it would "not be possible for Biotronik to use its cardiac implant devices in the manner contemplated by the Commission for 8 to 12 months." *Id.*

However, Biotronik's April 8, 2002, Petition for Reconsideration or Waiver of the OET Letter Order states that: "Scheduled messaging is programmable as ON or OFF," demonstrating that at least as early as April 8, 2002, Biotronik was able to turn off scheduled messaging and comply with OET's order. *See* Biotronik 2002 Petition for Waiver at 4.

²⁷ Biotronik's Belos units actually transmit more often than stated in the Request for Waiver. While the Request for Waiver states that the Belos devices transmit the same message seven (7) times (*see* Request for Waiver at 7), the Application to the FCC for Equipment Authorization of the Belos units states that the devices "may be programmed to send up to 10 repetitive transmissions of identical data at a programmed time interval." *See* Belos Technical Manual at 62, Equipment Authorization Application for Belos units, FCC ID: PG6BELOS-T.

In addition, the Belos Equipment Authorization Application discloses Belos power levels that are 8 dB greater than the level stated in Biotronik's Request for Waiver.

Thus, Biotronik's initially stated operating parameters are clearly subject to change in a manner that is likely to raise additional compatibility problems for operation in the MICS band.

(10 %) of the periodic scheduled transmissions monitored during a clinical study were not successfully received.²⁸ In an apparent effort to address this reliability issue, Biotronik has increased the transmit power levels and increased the number of repeat messages.²⁹ While these modifications may lessen the impact of interference from METAIDS users, they increase the risk of interference to MICS-compliant equipment and non-compliant Biotronik-like devices.

On the other hand, MICS-compliant implants are able to engage in bi-directional communications with external equipment and transmit only when there is an available channel and receiver. Thus, MICS-compliant implants do not need to re-transmit the same message repeatedly to increase the probability of success.

Not only does Biotronik's scheme increase the likelihood of interference to MICS-compliant equipment (and other Biotronik devices), it also leads to unnecessary battery drain. Unnecessary battery drain is not in the best interests of the implant patient since the greater the battery drain, the shorter the implant lifetime. Biotronik's Request offers additional detail on the horrors of battery drain issues.³⁰

If what Biotronik says in its Waiver and Comments with regard to the life-saving ability of its Home Monitoring feature is true, it provides further support for Medtronic's position that periodic scheduled transmissions must be implemented in accordance with the MICS regulations.

²⁸ The Value of Permanent Follow-up of Implantable Pacemakers – First Results of a European Trial, K. Wallbrück, et al., Biotronik GmbH, Technology & Service Center, Biomedizinische Technik (Berlin) 47 Suppl. 1, Part 2 (2002).

This is substantially lower than the “99.999% percent chance of transmission success” claimed in the Request for Waiver. Request for Waiver at 7.

²⁹ See n.27, *supra*.

³⁰ See Request for Waiver at 9-10.

Biotronik says that its medical professionals rely heavily on its devices to monitor the day-to-day condition of cardiac patients, as they use the daily reports to “effectively and reliably diagnose serious heart conditions early” and “save lives.”³¹ This is all the more reason to uphold the MICS regulations, which require implementation of LBT systems to ensure the successful receipt of implant transmissions.

CONCLUSION

For the reasons put forth in Medtronic’s Opposition and these reply comments, as well as the “very real” interference concerns of NTIA, the instant Request for Waiver should be denied.

Respectfully submitted,

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³¹ Biotronik Comments at 4-5. The transmissions are seemingly more important than stated in the company’s medical journal advertisements. Curiously, Biotronik’s advertisement, which ran in the monthly PACE Journal for the past year states that the Home Monitoring implants are “Not for Diagnosis – The data transmitted by Home Monitoring are not suitable for diagnosis ...” See Ex. A. to Opposition.

Certificate of Service

The undersigned hereby certifies that, on the date below, the foregoing REPLY
COMMENTS OF MEDTRONIC INC., was sent to these persons via electronic mail.

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