BEFORE THE

FEDERAL COMMUNICATIONS COMMISSION

WASHINGTON, DC 20554

In the Matter of	
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

REPLY COMMENTS OF MEDTRONIC, INC.

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SUMMARY

The FCC's proposed allocation of the 401-402 and 405-406 MHz wing bands for use by wireless implantable and body-worn medical device technology received wide-ranging support in the opening round of comments. Healthcare professionals, medical device manufacturers, integrated circuit manufacturers, trade associations, and numerous Americans are urging the FCC to implement the proposed regulations as soon as possible. As these parties recognize, the Commission's proposed two-tiered operational structure in the wing bands will enable the successful development of innovative medical devices and healthcare applications, such as Body Area Networks ("BANs"), which will improve patients' quality of life. The proposed allocation also offers the opportunity of international spectrum compatibility, providing the international traveler with access to advanced wireless medical services when at home and abroad.

The technical requirements that Medtronic proposed for operations in the wing bands should be adopted. *First*, wing-band operations should be licensed by rule, like the existing core band allocation, so that these important medical communications systems are protected from interference from other users. *Second*, the FCC should maintain the eligibility rules requiring these RF devices to be operated by, or at the direction of, a "duly authorized health care professional." This requirement will preserve the high quality of service that the MedRadio band requires and maintain control over the deployment of specialized MedRadio devices. *Third*, the FCC should implement the 100 kHz maximum emission bandwidth and maximum out-of-band emission levels proposed by Medtronic for wing band operations because they will support successful deployment of a large number of high data rate (*e.g.*, 100 kbps) body-worn sensors and implantable devices in close proximity. The 2 MHz allocation would thus provide 20

available “channels” and allow BANs supporting communications among multiple body sensors, implantable medical devices, and associated peripheral equipment.

In addition, the rules requiring Listen Before Talk (“LBT”) and Adaptive Frequency Agility (“AFA”) must be maintained in the core 402-405 MHz band. Many parties, including Medtronic, endorse the FCC’s plan to maintain the existing interference avoidance protocols in the core 402-405 MHz band because these protocols can reliably support the continued growth of wireless medical applications well into the future.

Finally, only implantable medical devices that support LBT/AFA and external devices that act as programmer/controllers and support LBT/AFA should be permitted in the core 402-405 MHz band at this juncture. If all types of body-worn medical devices were permitted in the core band at this time, the usefulness of the band for implantable medical devices would be adversely impacted. These types of external devices, which do not have the same battery drain and transmit power restrictions as implantable devices, could unnecessarily increase the interference in the band and subsequently degrade real-time communications from active implantable medical devices – the fundamental application for the core band.

Accordingly, the FCC should promptly authorize wireless medical operations in the wing bands in accordance with the proposals in the NPRM and Medtronic’s Petition for Rulemaking and maintain the well-established core band requirements given the extensive research and development effort that was required to design and deploy fully compliant medical communications devices and associated equipment.

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The Commission's Notice of Proposed Rulemaking in the above proceedings[1] received strong support from medical professionals, medical equipment manufacturers, radio frequency ("RF") integrated circuit manufacturers, trade associations, and interested Americans. Each explains that the FCC's proposed allocation of the 401-402 and 405-406 MHz wing bands will enable a wide range of body-worn, implantable, and associated external medical equipment that uses wireless communications to offer improved performance and enhanced patient services. Therefore, the FCC has ample reason to allocate promptly the additional 2 MHz of spectrum as

[1] *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, ET Docket No. 06-136, *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, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, FCC 06-103 at ¶ 1 (July 18, 2006) ("MedRadio NPRM").

proposed in the NPRM. As one commenter aptly notes, doing so "will likely foster new research and development [into] new technologies. There is little downside . . . increase the spectrum."[2]

I. THE FCC SHOULD ALLOCATE THE 401-402 AND 405-406 MHZ WING-BANDS FOR WIRELESS IMPLANTABLE AND BODY-WORN MEDICAL DEVICE TECHNOLOGY.

Opening commenters strongly support the Commission's proposal to authorize short-range wireless medical device operations in the "wing" bands surrounding the core 402-405 MHz Medical Implant Communications Service ("MICS") allocation.[3] These parties appreciate the FCC's firm recognition that the nature and pace of development of novel and more capable medical technologies have fueled the need for additional spectrum to accommodate new therapeutic and diagnostic concepts in implanted and body-worn medical devices.[4]

Intel, for example, believes that the expanded MedRadio band "would foster a new ecosystem of personal medical devices that could greatly improve the quality of life for many patients" through providing remote monitoring and treatment of "chronic diseases, cognitive decline disorders, post operative care, [and] infant care."[5]

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[2] Comment of Scot DeCristofaro (Aug. 7, 2006).

[3] *See* MedRadio NPRM at ¶ 20 (defining the 401-402 MHz and 405-406 MHz bands as the "wing" bands and the existing 402-405 MHz MICS band as the "core" portion of the proposed MedRadio band).

[4] *See* MedRadio NPRM at ¶ 3.

[5] Intel Comments at 2 (Oct. 31, 2006). The 401-402 and 405-406 MHz allocation will support advances in telemedicine, providing individuals located in remote areas of the country with access to "medical specialists in a variety of practices, including cardiology, pediatrics, and radiology, without leaving their homes or communities." *See Rural Health Care Support Mechanism*, Order, FCC 06-144, WT Docket No. 02-60 (Sept. 29, 2006); *see also* Medtronic Petition for Rulemaking at 4-5 (noting that telemedicine will provide physicians improved access to medical data so when patients travel into the office they will experience less down time and increased quality time).

As AMI Semiconductor explains, "developers are investigating the incorporation of wireless body-worn sensors to monitor patients' vital signs, eliminating a wired connection and providing additional patient mobility."[6] Such vital signs "may include temperature, pulse, respiration, blood pressure, blood oxygen saturation, heart data and even brain activity."[7] In this regard, the comments filed by GE Healthcare are particularly prescient:

> [I]t should be possible at some point in the near future for every patient to be monitored wirelessly inside and outside the hospital or health care facility setting; for the majority of the measurements to be taken using non-invasive, miniature wireless devices; for centralized enterprise monitoring to be the rule and not the exception and for health care professionals, regardless of location, to always have ready access to the information they need to make critical decisions about the treatment and care of their patients.[8]

The MedRadio allocation will help the medical community move toward this future.

The opening commenters strongly recommend that the FCC's regulations governing wing-band operations must proactively address the spectrum challenges to be faced by the next generation of wireless medical devices given the wide array of spectrum environments that the increasingly mobile patient will encounter. Indeed, self-regulating interference management techniques will be vitally important to physicians using the new service to configure, control, and collect data from implantable and body-worn patient medical devices. In the case of Body Area Networks ("BANs"), these networked medical devices will need to communicate in a highly coordinated fashion while avoiding RF signals from nearby unaffiliated devices. As these advanced medical systems proliferate, finding open spectrum will become increasingly difficult,

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[6] AMI Semiconductor at 2 (Oct. 30, 2006).

[7] *Id*.

[8] GE Healthcare Comments at 3-4 (Oct. 31, 2006).

especially in clinical settings and assisted living facilities, and proper implementation of Listen Before Talk ("LBT") or Adaptive Frequency Agility ("AFA") protocols will be essential.

A. **The FCC's Proposed Two-Tiered Operational Structure For The Wing Bands Will Enable The Successful Development Of Body Area Networks And Other Useful Medical Devices.**

Medtronic agrees with the Commission that implementing two-tiers of operations in the wing bands will accommodate a broad array of short-range wireless medical applications. The first tier would support RF medical devices that perform LBT and AFA because they transmit more often or require higher transmit power than second tier devices.[9] The second tier would support devices that do not perform LBT and AFA so long as they operate with lower power and a lower duty cycle ("LPLDC") – that is, limit their power to 250 nanowatts EIRP, and operate with a 0.1% duty cycle (that is, no greater than 3.6 seconds of total transmission time within any one-hour period).[10]

The FCC's proposed two-tiered operational structure in the wing bands gives medical device manufacturers options to support applications with different communications urgency and reliability needs. Many parties praise the FCC's acknowledgment that the wing bands are "well-suited for implanted and body-worn medical radio devices for the same reasons 402-405 MHz was originally designated for MICS."[11] The Commission recognizes, that the "provision of contiguous spectrum will provide for the maximum efficiency of design and operation,"[12] allowing manufacturers to design devices that make use of both the wing bands and the core

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[9] MedRadio NPRM at ¶ 24.

[10] *Id*. at ¶ 25.

[11] *See* MedRadio NPRM at ¶ 20; Medtronic Comments at 4-6 (Oct. 31, 2006); Zarlink Semiconductor Comments at 3 (Oct. 31, 2006).

[12] MedRadio NPRM at ¶ 20.

band depending upon the device type and its particular communications needs.[13] As Zarlink Semiconductor explains:

> Because these bands are directly adjacent to MICS and the FCC's proposal for the bands [is] based, in part, on the MICS smart radio requirements, Zarlink would be able to take advantage of technology advances and lessons learned from its previous MICS developments.[14]

Intel, in particular, has studied the FCC's proposal closely and agrees with the agency that LBT and LPLDC operation in the wing bands, as proposed in the NPRM, can coexist successfully. Intel recognizes that LBT "greatly increase[s] the user density" in clinical environments because "relying on physical separation alone to support multiple users is not practical."[15]

Many parties agree that the FCC's proposed two-tiered operational structure "reflect[s] a reasonable balance between the operational capabilities needed for such devices to function properly and the need to minimize the risk of interference" to other devices in the wing bands.[16] Spectrum congestion is a concern to Dr. Crossley, a MICS pioneer, who "strongly encourages" the FCC to provide for reliable communications over the long term because the "[u]se of wireless technology will be quite intensive in the typical medical facility."[17] The Commission's

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[13] *See, e.g.,* AMI Semiconductor at 4 (accommodating LPLDC devices in the wing bands will enable simple and low-cost body-worn medical wireless devices and allow "more individuals to benefit from improved medical care").

[14] Zarlink Semiconductor Comments at 3.

[15] Intel Comments at 8; *see also* Timex Comments at 2 ("It is possible that this spectrum could become quite crowded. Thus, the frequency monitoring techniques proposed by the FCC are needed to ensure successful communications by medical devices that will be on the air more often.").

[16] MedRadio NPRM at ¶ 25.

[17] *See* George H. Crossley III, M.D., FHRS, FACC Comments (Oct. 26, 2006).

new service, if implemented as proposed in the NPRM, will allow medical professionals and their patients "to utilize potential life-saving medical technology without causing interference to other users of the spectrum."[18]

B. Use Of This Spectrum By Low-Power RF Medical Devices Would Be Compatible Internationally.

The operations that the FCC proposed in the NPRM already have been incorporated into ETSI TR 102 343 (V1.1.1) for ultra-low power medical applications in the 401-402 and 405-406 MHz bands.[19] FCC allocation of the 401-402 and 405-406 MHz bands for the MedRadio service would encourage worldwide harmonization of a service band that the ITU-R has found to be compatible with the incumbent users of the band, METAIDS.[20]

As Timex, Zarlink Semiconductor[21] and others point out, international compatibility would allow development costs to be spread among multiple national markets, thereby lowering healthcare costs. Compatibility across borders also would serve the public interest by offering

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[18] MedRadio NPRM at ¶ 7; *see also id*. at ¶ 11 (Commission's wing band regulations "are designed to ensure compatibility among multiple uncoordinated" medical devices in close proximity).

[19] *See* ETSI TR 102 343 V1.1.1 (2004-07), Technical Report, Electromagnetic Compatibility And Radio Spectrum Matters (ERM); Ultra Low Power Active Medical Implants (ULP-AMI) operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; System Reference Document (including the same two tiers of operation in the wing bands, as proposed in the Commission's NPRM).

[20] *See* MedRadio NPRM at ¶ 15; Recommendation ITU-R SA.1346, Sharing Between The Meteorological Aids Service and Medical Implant Communications Systems (MICS) Operating in the Mobile Service In the Frequency Band 401-406 MHz.

In the *Report and Order* adopting the core band rules at 402-405 MHz, the Commission highlighted the ITU-R recommendation as a basis for sharing the band with the METAIDS users and in deciding to "designate the MICS as a shared, secondary operation in the 402–405 MHz band." 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, 21044 (1999) ("MICS Report and Order").

[21] *See* Timex Comments; Zarlink Semiconductor Comments at 4.

the international traveler, with MedRadio-based implanted or body-worn medical device technology, an enhanced degree of freedom by ensuring that the traveler can receive appropriate medical attention at home and abroad.

C. The FCC Should Adopt The Technical Requirements That Medtronic Proposed For Operations In The Wing Bands.

In this section, Medtronic responds to technical issues that several parties addressed in the opening round of comments.

Licensed Operations. Like operations in the existing 402-405 MHz core band, wing band operations should be licensed by rule in order to provide these important medical communications with protection against interference from unlicensed operations.[22] As Intel notes, the 401-406 MHz band is ideally suited for these applications as "medical sensors cannot bear the risks associated with operating in unlicensed spectrum."[23] This is especially true given many parties' express need for the MedRadio service to carry data that is critical to the patient's life.

Use Restrictions & Eligibility. Medtronic agrees with Intel that it "would be inappropriate to allow the MedRadio spectrum to be used by sensor devices that may arguably transmit physiological data, but are used for general fitness where the necessity of the data transmission is not life critical."[24] Devices used in general fitness applications can, and, in fact, currently do operate successfully in unlicensed spectrum. Intel correctly notes that unlicensed

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[22] *See* Partners Healthcare Comments at 5; Medtronic Comments at 19; *see also* MICS Report and Order (Because "MICS is a very low power, short-range radio service operating within a closed environment . . . individual licensing . . . would be costly to the public and administratively burdensome.").

[23] Intel Comments at 4.

[24] *Id*. at 5.

spectrum should be used for these types of physiological sensors, and therefore requests that the FCC require MedRadio devices to comply with the Eligibility Rules in the proposed Section 95.1601 that:

> Duly authorized health care professionals are permitted to operate [MedRadio] transmitters. Persons may also operate [MedRadio] transmitters to the extent the transmitters are incorporated into medical devices that are used by the person at the direction of a duly authorized health care professional; this includes medical devices that have been implanted in that person or placed on the body of that person by a duly authorized health care professional. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services.[25]

This rule will help to preserve the high quality of service required by medical device communications.

Thus, the Commission should reject requests that the FCC relax this requirement in order to allow more "widespread adoption of MedRadio devices."[26] Uncontrolled dissemination of other types of devices could eventually destroy the usefulness of the band for medical applications and relegate it to little more than another "Part 15-like" band albeit with *protection from Part 15 devices*.

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[25] Medtronic Petition for Rulemaking at A-13 (proposing new Rule Section 95.1601 – Eligibility which parallels the MICS band eligibility rules in Section 95.1201). Opening the band up to general use by the population will impact the band's utility for medical applications.

Similarly, the ban on voice communications should be extended to the full MedRadio band. *See* Medtronic Petition for Rulemaking at A-3, A-6, A-13, & A-15 (following the MICS Rule Sections 95.401, 95.631, 95.1209, & 95.1215).

[26] AMI Semiconductor Comments at 3.

100 kHz Maximum Emission Bandwidth. The maximum authorized emission bandwidth for operations in the 401-402 and 405-406 MHz wing bands should be 100 kHz.[27] Given that the wing bands comprise 2 MHz of spectrum, a 100 kHz bandwidth would theoretically provide at least twenty communication "channels," each of which could support data rates 100 to 300 kbps[28] for body-worn and implantable medical devices.[29]

In this way, a 100 kHz maximum emission bandwidth would support a large number of transmitting devices in close proximity, each with a data rate sufficient to support the data transfer requirements for body-worn sensors and other medical devices comprising BANs.[30]

Out-of-Band Emissions from The Wing Bands Into The Core Band. As Medtronic pointed out in its opening comments, the performance of core-band systems operating at 402-405 MHz will be materially degraded if wing band devices are permitted to inject high levels of out-of-band ("OOB") emissions into the core band due to the adjacent channel spectral regrowth

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[27] *See* Medtronic Comments at 9-10; Medtronic Petition for Rulemaking. This proposal is consistent with the draft ETSI standard. *See* ETSI TR 102 343 V1.1.1 (2004-07), *infra*.

[28] *See* Intel Comments at 7.

[29] Consider, for example, METAIDS radiosondes that have an emission bandwidth of approximately 300 kHz and a frequency drift of potentially one or more MHz. If a METAIDS radiosonde were to drift into one of the wing bands, a significant number of non-blocked "channels" would be available with a 100 kHz maximum emission bandwidth.

[30] Several parties ask the FCC to adopt a 300 kHz maximum channel bandwidth in the wing bands based on a claimed need for "consistency" with the MICS band. *See, e.g.*, AMI Semiconductor Comments; Biotronik Comments (Oct. 31, 2006). These parties fail to recognize, however, that devices operating in the wing bands and devices operating in the core band will support different, but complementary, medical functions.

A 300 kHz maximum emissions bandwidth is appropriate for the core band, which was designed to support life-critical, time-sensitive wireless communications from implantable medical devices, including the analysis of real-time electrocardiographs transmitted during implantation. A 100 kHz maximum emissions bandwidth is appropriate for the wing bands because of the large number of "channels" available to support co-located patients, each of which may have multiple sensors or devices operating simultaneously.

phenomena.[31] For this reason, Medtronic proposed tighter OOB emissions levels for wing band operations than the OOB emission levels that apply to core band devices because the expected proliferation of wing-band devices could essentially make several hundred kHz of core MICS band spectrum unavailable to core band devices.

St. Jude Medical also recognizes that "it is essential to ensure minimal spillover" from the wing bands into the core 402-405 MHz band in order to avoid "increasing the noise level"[32] in the core band. For example, uncurtailed OOB emissions from the body-worn device can interfere with transmissions to the implantable medical device from an external programmer controller in the case of a patient with multiple body-worn devices that operate in the wing bands and one or more implantable medical devices that operate in the core band. The problem is exacerbated by the fact that body-worn devices operating outside the core band, irrespective of whether they use LPLDC (250 nanowatts) or LBT/AFA (25 microwatts) for spectrum access, may be transmitting at the maximum allowed power while the implantable core band device will need to transmit at much lower power to limit implant battery drain.[33]

A number of well-known techniques are available to limit OOB emissions into the core band. *First*, a smaller transmit bandwidth can be used or alternatively a guard band adjacent to the core band can be implemented. The 100 kHz emission bandwidth limit that Medtronic proposed effectively limits the bandwidth of spectral artifacts (*i.e.*, regrowth) caused by

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[31] *See* Medtronic Comments at ¶ 10.

[32] St. Jude Medical Comments at 3.

[33] *See* Medtronic Grant of Equipment Authorization LF5MICSIMPLANT, with 100 nanowatts output power.

nonlinear amplification stages. It is well known that the bandwidth of spectral regrowth is proportional to the bandwidth of the transmitted digital signal.[34]

Second, a manufacturer can choose to limit the modulation to constant envelope types (*e.g.*, frequency shift keying) for operations near the MICS band, thereby limiting the spectral artifacts produced by nonlinear amplification stages.

Third, if the application allows it, the manufacturer may reduce OOB emissions by simply transmitting with less power. A wide variety of body-worn applications are likely to operate adequately with substantially less transmit power than the maximum permitted.

High levels of OOB emissions into the MICS band cannot be justified based on the LBT/AFA function selecting clear spectrum in other portions of the MICS band because the spectrum may not be available. Thus, unless the OOB emissions into the core band are limited to 100 microvolts per meter measured at three meters,[35] there is a strong likelihood that OOB emissions from wing band devices will disrupt communications between implantable medical devices and their associated programmer/controller given the close physical proximity of RF medical devices that are located on and inside of a patient.

Field Strength Reduction for Body-Worn Devices. In its opening comments, Medtronic explained the need to account for the body absorption of signals in assessing the field strength levels from body-worn devices when the devices are measured on an Open Area Test

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[34] Kamilo Feher, DIGITAL COMMUNICATIONS MICROWAVE APPLICATIONS 134, Fig. 6.16 (1997).

[35] *See* Medtronic Petition for Rulemaking at A-7 to A-8 (proposing revisions to Section 95.635).

Site ("OATS"). Medtronic proposed two acceptable methods of accounting for this phenomenon,[36] and respectfully requests that the Commission formally adopt both methods.

D. **The Operations Proposed By Biotronik And DexCom Can Be Supported In The Wing Bands, In Accordance With the FCC's Proposals.**

There is no sound technical reason why the non-LBT operations proposed by Biotronik and DexCom cannot be supported in the wing bands, in accordance with the proposed low-power, low-duty-cycle ("LPLDC") mode of operation and 100 kHz maximum emission bandwidth.

The power level, duty cycle, and bandwidth limits proposed for the LPLDC mode are more than sufficient for Biotronik's application.[37] DexCom's device also can operate pursuant to the LPLDC mode so long as it lowers its transmit power to the reasonable level proposed by the FCC.[38] In fact, Biotronik's implantable medical device that uses a transmit power level lower than 2.5 *nano*watts EIRP (as referenced on its FCC grants) belies DexCom's claimed need for 10 *micro*watts EIRP – a power level that is four thousand times greater.[39] Indeed, Intel has

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[36] *See* Medtronic Comments at 10-11.

[37] *See* Biotronik Grant of Equipment Authorization PG6CYLOS, noting an Output Power Level of 2.4 nanowatts EIRP and Emission Designator of 46K0F1D, which corresponds to a 46 kHz emission bandwidth. *See also* Biotronik Grant of Equipment Authorization PG6BA0T, noting an even lower Output Power Level of 1.2 nanowatts EIRP and the same Emission Designator of 46K0F1D and associated 46 kHz emission bandwidth. The proposed duty cycle of 0.1% for the LPLDC mode is more than adequate for Biotronik's application.

[38] *See* MedRadio NPRM at ¶ 25 (proposing 250 nanowatt power level); *and see* DexCom Grant of Equipment Authorization PH29400, noting an Output Power Level of 10 microwatts EIRP and Emission Designator of 100KA1D, which corresponds to a 100 kHz emission bandwidth. The proposed duty cycle of 0.1% for the LPLDC mode also is more than adequate for DexCom's application.

[39] There can be no question, therefore, that the (wing-band) LPLDC power level proposed by the FCC of 250 nanowatts EIRP, which is 20 dB greater than the 2.5 nanowatts that Biotronik uses, is more than sufficient for the RF medical applications that Biotronik and DexCom offer today and that Medtronic and others will offer in the future.

determined that emissions levels at 25 microwatts EIRP can reliably support distances in the tens of meters range.[40] Thus, DexCom's request that its external transmitter be permitted to continue operating at 10 microwatts EIRP without LBT/AFA capability requires close Commission review.[41]

The argument that these particular device applications need to be placed in the core MICS band because that band is quieter than the wing bands does not withstand scrutiny.[42] In

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[40] *See generally* Intel Comments. On a related note, Boston Scientific's ("BSC's") request to allow power levels of 0 dBm EIRP from implantable medical devices should not be seriously entertained. *See* BSC Comments at 9-11 (Oct. 31, 2006). The MedRadio service is designed for short range communications to peripheral medical equipment that is several meters away. The distances that BSC would like to operate over will introduce added complexity and power drain to implants, impact the usefulness of LBT and AFA, and limit the general usefulness of the band for medical BANs.

Similarly, BSC's request for permission to aggregate up to five 300 kHz channels should be rejected, as it would permit a single device to occupy 1.5 MHz (or half of the current 402-405 MHz core band allocation), leaving too little spectrum for other nearby devices. Curiously, BSC argues, in one breath, that it needs 12 MHz more spectrum for medical implant communications beyond what is already allocated in the core band, and in the next breath asserts that the core band allocation is under utilized. *See* BSC Comments at 7.

[41] Well-known equipment design techniques, such as antenna diversity, can be utilized in the external receiver to greatly improve link reliability performance without increasing implantable device complexity. For example, two branch antenna selection diversity typically provides over 9 dB of link margin improvement in common indoor propagation environments. *See* W.C. Jakes, *A Comparison of Specific Space Diversity Techniques for Reduction of Fast Fading in UHF Mobile Radio Systems*, IEEE TRANSACTIONS ON VEHICULAR TECHNOLOGY, Vol. VT-20, No. 4 at 81-93, Nov. 1971; T.S. Rappaport, WIRELESS COMMUNICATIONS PRINCIPLES AND PRACTICE 327 (1996).

DexCom's higher-power operations, which use an external RF transmitter, will cause interference to implantable medical devices that perform LBT and AFA. Moreover, allowing DexCom's approach in the core band would occupy another "channel" within the core band, leaving less spectrum for fully compliant operations.

[42] *See* Biotronik Comments at 13-14 ("optimal location for LPLDC access is the center of the existing MICS band, i.e., . . . 403.65 MHz"); St. Jude Medical Comments at 2.

Biotronik's claims that LPLDC should be permitted in the MICS band based on Biotronik's own computer-based modeling are highly questionable. Biotronik fails to provide a full set of the parameters used in its modeling, including parameters relating to wall losses and (Continued)

fact, the 403.5 MHz to 403.8 MHz frequency band of operation requested by Biotronik is, in fact, very close to the nominal center frequency of METAIDS radiosondes – the primary occupants of the 401-406 MHz band.[43] Therefore, it is more likely that Biotronik's device operating at 403.5 to 403.8 MHz would suffer interference from a radiosonde than it would if it were operating in the wing bands.

The FCC should require devices that do not comply with the core band rules requiring system operation using LBT and AFA to operate in the wing bands, which specifically support this mode of operation. As Partners Healthcare points out:

> The temporary waivers granted by the Commission suffice for today's medical device environment. However, as the numbers of medical devices grow with anticipated use, we believe it possible that harmful interference will become far more likely.[44]

Notwithstanding the foregoing, should the FCC decide to permit LPLDC operations in the MICS band, it should follow the terms of the proposal in Europe as set forth by St. Jude

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the RF environment, thus making it impossible to test the model. Moreover, Biotronik's analysis disregards the potentially detrimental impact of interference, particularly to higher duty-cycle, real-time transmissions from implanted devices in the MICS band.

[43] *See* Martin Cave, et al., *An Independent Audit for Her Majesty's Treasury*, Dec. 2005 *available at* http://www.spectrumaudit.org.uk/pdf/caveaudit.pdf *last accessed* Dec. 4, 2006 (noting that METAIDS equipment operates within the 400-406MHz band and that radiosonde usage is "concentrated in the middle of the band to avoid interference at the margins"); *see also* World Meteorological Organization, *Requirements of the Meteorological Aids Service In The Band 401-406 MHz*, Resolution 219, Mar. 2, 1999 at 77 (recommending that MetAids operations be confined "within the band 403 to 406 MHz by the year 2010"). This suggests that the lower 401-402 MHz wing band may actually be better suited for Biotronik's and DexCom's LPLDC operational mode; *and see* Sippican Data Sheet for Mark II Microsonde™ (noting that while the device operates over the range 400-406 MHz, 403 MHz is the "nominal frequency").

[44] Partners Healthcare System Comments at 7.

Medical and Zarlink Semiconductor.[45] The FCC should not institute the overreaching proposal that appears in Biotronik's comments because it goes well beyond the Systems Reference Document published by ETSI for MICS-band LPLDC operation.[46]

II. THE CORE 402-405 MHZ BAND RULES THAT REQUIRE LISTEN BEFORE TALK AND ADAPTIVE FREQUENCY AGILITY MUST BE MAINTAINED.

Many commenting parties, including Medtronic, strongly concur with the FCC's affirmation that the core 402-405 MHz MICS allocation should be preserved for medical devices that Listen Before Talk ("LBT") and support Adaptive Frequency Agility ("AFA") to "protect their function and to reduce the risk that they would be subject to interference," especially as RF medical device "spectrum use intensifies."[47] It would be unwise to upset rules that apply to the burgeoning RF medical implant industry, for medical device manufacturers, integrated circuit

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[45] *See* St. Jude Medical Comments (Oct. 27, 2006) at 1; Zarlink Semiconductor Comments at 2. Any such access in the core band should be limited to: (1) spectrum between 403.5 and 403.8 MHz; (2) implant transmissions only; (3) 0.01 % maximum duty cycle (that is, no more than 360 milliseconds transmission time during any one-hour period); (4) 100 nanowatts ERP transmit power; (5) no more than 10 transmissions per hour, and (6) devices may not use the medical implant event exception provision for spectrum access. *See* ETSI TR 102 434 V1.1.1 (2005-06), Technical Report, *Electromagnetic Compatibility and Radio Spectrum Matters; Short Range Devices (SRD); Alternative Interference Mitigation Technologies to Listen Before Talk (LBT) for Ultra Low Power Active Medical Implants (ULP-AMI) Operating From 403,5 to 403,8 MHz With A Duty Cycle Of Less Than Or Equal To 0,01%; System Reference Document*.

Biotronik's proposed use of the 403.5 to 403.8 MHz "channel" as a beacon channel should be rejected because it contrary to the terms of the FCC's waiver and the European standard. Such operations, however, may be supported by the FCC's proposed LPLDC operational mode in the wing bands.

[46] *See* ETSI TR 102 434 V1.1.1 (2005-06); *see also* AMI Semiconductor Comments at 4 ("Harmonization between FCC and other international standards should be given high priority.").

[47] MedRadio NPRM at ¶ 24 (proposing to "preserve [the core MICS] block of spectrum at 402-405 MHz for the more critical devices … that employ frequency monitoring both to protect their function and to reduce the risk that they would be subject to interference"). The FCC has repeatedly recognized the benefits of self-regulating spectrum sensing techniques. *See, e.g., Unlicensed Operation in the TV Broadcast Bands*, First Report And Order And Further Notice Of Proposed Rulemaking, ET Docket No. 04-186, FCC 06-156 (Oct. 18, 2006).

manufacturers, and the medical community have invested substantial time and effort researching, developing, and testing compliant RF-based products for the 402-405 MHz core band in reliance on the well established regulations.[48]

There will soon be a host of medical implant devices that take full advantage of the core band's ability to support time-sensitive, life-critical communications.[49] Medtronic has been distributing MICS-compliant products for some time, and other manufacturers have publicly announced that they too will be distributing MICS-compliant implants.

The 402-405 MHz core band has emerged as a worldwide band for active medical implant communications based on the LBT/AFA channel access protocol. The European Union and the European Free Trade Association countries, Australia, New Zealand, Japan, and Canada[50] have adopted regulations generally consistent with the FCC's MICS rules, which have been in place since 1999.[51]

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[48] *See* MedRadio NPRM at ¶ 24.

[49] *See id*.

[50] *See* European Standard ETSI EN 301 839 V1.1.1 (2002-06), *Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1* at 29-38; Australia Radiocommunications (Low Interference Potential Devices) Class Licence 2000 (No. 1), July 26, 2006 *available at* http://www.acma.gov.au/ACMAINTER.1900810:STANDARD::pc=PC_297 *last accessed* Dec. 4, 2006; Short Range Devices Discussion Paper, Summary of Submissions and Conclusions, Dec. 2004, New Zealand Ministry of Economic Development, Radio Standards and Compliance, *available at* http://www.rsm.govt.nz/standards/notices/radio-stds/index2.html *last accessed* Dec. 4, 2006 (allocating 402 to 405 MHz for low-power biomedical telemetry applications and referencing FCC and ETSI regulations); Japan Cabinet Order for Enforcement of the Radio Law at Art. 6, ¶ 4, item 2-(4) (Cabinet Order No. 245 of 2001) (added frequency of Specified Low-Power Radio Station) *and* Japan Ordinance Regulating Radio Equipment at Art. 49-14, ¶ 1, item 2 (Radio Regulatory Commission Rules No. 18 of 1950) (added technical conditions for self-contained medical data transmission systems); Active Medical Implant Communications System Devices in the 402-405 MHz Band, Industry Canada, Spectrum Management and Telecommunications Policy, Radio Standards Specification, RSS-243, Issue 2, Nov. 2005 (Continued)

As the Timex Corporation and many others have explained: "Internationally compatible operations are a worthwhile goal, as they will enable individuals to use these wireless products whether at home or overseas, and they also allow for lower-cost production as the same products can be sold in multiple countries."[52]

Semiconductor manufacturers also explain the importance of the interference avoidance mechanisms that the FCC has in place for MICS. AMI Semiconductor explains that LBT capabilities greatly reduce "the possibility of interference between various MICS band devices . . . even for devices with very high duty cycle requirements."[53]

Indeed, ITU-R Recommendation SA.1346 explains: "International spectrum studies have shown that even with 3 MHz available only one or two channels will be usable in many environments [and in] the case of a clinic with multiple programmers, overall use of the band could approach 50% during business hours."[54]

NDI Medical deemed the FCC proposal to "maintain the existing MICS rules in this spectrum" a "good decision" because it ensures that there is an appropriate spectrum sharing

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available at http://strategis.ic.gc.ca/epic/internet/insmt-gst.nsf/vwapj/rss243e.pdf/$FILE/rss243e.pdf *last accessed* Dec. 4, 2006.

[51] *See* MICS Report and Order.

[52] Timex Corporation Comments. Nevertheless, the fact that the draft ETSI standard provides for LPLDC operation on one frequency within the core band should not compel the FCC to implement such operation. Without provision for LPLDC operation at 403.5 MHz, manufacturers designing product for use in both Europe and America would still have the option of designing equipment that would use LPLDC techniques in 401-402 and 405-406 MHz so that the equipment could function in Europe as well as in the United States. Thus, for devices to work in multiple regions of the world, the rules need not be *identical* in order to be *harmonious*.

[53] AMI Semiconductor Comments at 4.

[54] ITU-R Recommendation SA.1346, Recommendation No. 3, Annex 1 §§ 2.2, 2.4.

mechanism for more complex devices that have higher total data transfer needs.[55] NDI Medical went on specifically to encourage the FCC to maintain the "frequency monitoring" regulations in Section 95.628(a), as they will enable reliable operation in a "variety of environments and locations; not just in a clinical setting."[56]

The Cleveland FES (for "Functional Electrical Stimulation") Center noted that these RF capabilities for medical implants must be "immediately responsive" and "free from external interference" so that they will reliably support common actions such as grasping, standing, walking, and even bladder control and respiration.[57] As NDI Medical aptly notes, there will be long periods where the patient invokes no commands at all, and then periods of time where many commands are invoked almost continuously for minutes at a time.[58] Thus, a self-regulating channel sensing protocol such as LBT is essential to ensure reliable performance.

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[55] NDI Medical Comments.

[56] *Id.*. "[P]rescribing spectrum use by regulation is appropriate for 'uses that provide clear, non-market public interest benefits or that require regulatory prescription to avoid market failure.'" *See* GE Healthcare Comments at 12, quoting Spectrum Policy Task Force, ET Docket No. 02-135, Report (Nov. 2002) at 41; *id*. at 12-13 ("given the need for economies of scale to make the [Body Sensor Network] concept viable, it would not be appropriate to authorize such devices under a regime that is as flexible or non-prescriptive as the regime for many of the Commission's auctioned services (e.g., Part 27). While a substantial degree of flexibility is good, permitting too much flexibility – e.g., with no directions or restrictions on the type of services that can be provided and the technical parameters necessary to ensure robust and secure service – could make it impossible for equipment manufacturers to understand how the band will be used and how to engineer devices that can reliably coexist with others in the band.").

[57] Cleveland FES Center Comments; *see also* GE Healthcare Comments at 7 ("[T]he technology used to transmit the data must be frequency agile, capable of dynamically adapting to co-channel interference (in order to avoid interference caused by multiple nodes and hubs transmitting and receiving node/sensor-generated data from patients located in close proximity to each other) . . . .").

[58] NDI Medical Comments.

Echoing these concerns is Partners Healthcare System, one of the nation's premier biomedical research organizations as well as a major teaching affiliate of Harvard Medical School. Partners Healthcare explains that the proposed uses for medical wireless technologies:

> involve medical devices with functions critical to the health and well-being of the person using the device. Failure of the communications link in these anticipated systems could expose the user to the risk of injury or death, giving an entirely new meaning to the Commission's definition of "harmful interference."[59]

A. RF Implantable Medical Devices That Operate In The Core Band Should Be Separated From Unassociated Body-Worn And External Devices.

The MICS regulations and the proposed rules for the 401-402 and 405-406 MHz bands are aimed at supporting different, but often complementary, medical devices. Unlike most medical devices that are expected to operate in the wing bands, implantable medical devices operating in the core MICS band have far greater battery constraints. Given that wireless implantable medical devices must use the same power source for therapeutic and diagnostic operations as they use for communications, conserving implant battery life is critical. To limit power drain, RF-capable implantable medical devices must typically use transmit power levels substantially less than the maximum allowed levels.

As the FCC recognizes in the MedRadio NPRM, the regulatory structure for low-power wireless medical communications should foster an environment in which those devices with such power constraints that can least afford frequent battery replacements are operated in a manner that minimizes power consumption.[60] LBT and AFA must be utilized exclusively in the core

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[59] Partners Healthcare System Comments at 3.

[60] MedRadio NPRM at ¶ 24. The expenditure of power for body-worn sensor technologies, which would make extensive use of the wing bands, does not exact the same high price in terms (Continued)

MICS band to minimize the probability of receiving interference. Any interference that makes an implantable medical device seek another channel or retransmit data packets causes additional battery power drain (and can delay time-critical communications).[61] The current framework governing core band operations is appropriately structured to provide both for efficient spectrum management and minimal expenditure of precious battery power by implantable medical devices.

In addition, restoring implantable medical device functions when the battery becomes depleted is not simple and entails more risk to the patient than replacing batteries in body-worn devices. Batteries that power external or body-worn devices generally are readily accessible and replaceable by the patient. Battery replacement in implantable medical devices, however, often requires surgery and replacement of the entire device.

There is no question that wireless medical technologies need self-regulating spectrum management techniques that limit interference, enable reliable channel access in unused spectrum, and support multiple uncoordinated medical devices in environments where there will be a high concentration of patients in close quarters, such as hospitals, nursing homes, and assisted living environments.

B. Only MICS-Compliant Implantable Medical Devices And External Devices That Act As Programmer/Controllers And Perform LBT/AFA Should Continue To Be Permitted In The Core Band At This Juncture.

The core 402-405 MHz band should continue to be used only for implantable medical devices that comply with the current MICS rules. Despite requests for the FCC to allow all types

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of replacement expense and patient risk that replacement of batteries for implantable medical devices entails.

[61] "For a medical communication scheme to be usable, it must be both reliable and timely." *Ex Parte* Letter of Steven Greenberg, M.D., ET Docket No. 03-92, Dec. 13, 2003 (filed Jan. 8, 2004).

of body-worn device operations inside the core band, the FCC must only allow body-worn medical devices that act as programmer/controllers supporting LBT/AFA at this critical point in time.[62]

Medtronic and Boston Scientific agree that allowing all types of body-worn devices in the core band would impact the usefulness of the band for implantable medical devices.[63] Should body-worn devices be permitted in the MICS band and they proliferate as widely as many of the commenters believe, it will be impossible to undo the potential harm to current and soon-to-be deployed RF implantable medical devices, as these devices may be unable to find an available channel in the core band. While implantable medical devices are limited to ultra low level transmissions by virtue of their battery constraints, body-worn devices are not so limited. If the experience gained through device operations in the wing bands shows that implantable and body-worn devices can successfully co-exist, then the FCC can take steps to permit additional body-worn devices in the core band at an appropriate time in the future.

Intel, the world's largest semiconductor manufacturer and a leader in standards and technical innovation, recognizes the critical roles that LBT and AFA will play in the continued successful deployment of implantable medical devices. Interference avoidance mechanisms allow for the reduction in power consumption "to maximize battery life and minimize battery

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[62] MedRadio NPRM at ¶ 20; Medtronic Comments at 11-12. Intel has independently analyzed this issue and agrees with the Commission's proposal to keep non-LBT operations in separate bands. *See* Intel Comments at 8 ("One important aspect is that LBT devices and non-LBT devices be in separate bands. In theory, the non-LBT device will always talk without listening and the LBT device will not talk unless the frequency is quiet. Hence, if LBT devices are mixed with non-LBT devices, the result could be that the LBT devices seldom get a chance to make a transmission. Placing the non-LBT devices in the wing bands seems a reasonable thing to do.").

[63] *See* BSC Comments at 7-8. In fact, BSC has asked the FCC for an additional 12 MHz of spectrum reserved exclusively for medical implant communications systems, claiming that future medical implant applications will require a wide swath of spectrum. *See* BSC Comments at 6-8.

size."[64] And, their use ensures that the "overall reliability of the data transmission [is] kept high."[65] Opening the core band to all types of body-worn devices while the band is still in its "nascent stages"[66] could have an adverse impact on the continued development and successful future deployment of RF implantable medical devices.

As medical professionals increasingly take advantage of the ease of use and effectiveness of wireless connectivity, their primary focus must be on the administration of therapy to patients and the analysis of medical data from patient devices. The spectrum management techniques set forth in the NPRM coupled with the additional recommendations championed by Medtronic and others, as outlined above, will ensure beneficial use of this limited amount of short-range wireless medical spectrum well into the future.

III. THE OVERWHELMING MAJORITY OF COMMENTING PARTIES FAVOR CLOSE COLLABORATION AMONG THE FCC, FDA, AND INDUSTRY.

Almost all of the parties that commented on the issue, strongly encouraged the FCC and the Food and Drug Administration ("FDA") to work more closely together to manage the impact of electromagnetic interference ("EMI") on medical devices.

As the FCC explained in the MedRadio NPRM, implantable and body-worn devices can be "adversely affected" when they are brought into "unpredictable electromagnetic environments, both within and beyond the health care setting."[67] The Commission noted that

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64 Intel Comments at 4.

65 *Id*.

66 MedRadio NPRM at ¶ 25.

67 *Id*. at ¶ 45.

patients with implanted or body-worn devices have increased susceptibility when they "congregate in a health care facility, resulting in a particularly high local density of use."[68]

The Advanced Medical Technology Association ("AdvaMed"), the American Association of People with Disabilities ("AAPD"), Medtronic, Biotronik, and Partners Healthcare agree that increased interaction between the FCC and the FDA, including representatives from the FDA's Center for Devices and Radiological Health ("CDRH") that have experience with active implantable medical devices, would help to bring about improved methods of addressing EMI issues.[69]

These parties also generally agree that FCC/FDA interaction should include a medical device industry liaison (*e.g.*, AdvaMed), medical professionals and the general public to analyze different methods of limiting the impact of EMI on medical devices and publish the studies and conclusions on their respective websites and in news releases.

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[68] MedRadio NPRM at ¶ 45.

[69] *See* AdvaMed Comments; AAPD Comments; Medtronic Comments; Biotronik Comments; Partners Healthcare Comments.

IV. CONCLUSION

The Commission's proposal to allocate the two 1 MHz wing bands at 401-402 and 405-406 MHz received strong support from almost every party who filed comments, thereby paving the way toward swift adoption of the proposals to support the next generation of wireless medical devices. In addition, many parties, including Medtronic, endorsed the FCC's plan to maintain the existing interference avoidance protocols in the core 402-405 MHz band, because they enable reliable communications and will support the continued growth of wireless medical applications. Therefore, the FCC should promptly authorize wireless medical operations in the wing bands in accordance with the proposals in the NPRM and Medtronic's Petition for Rulemaking.

Respectfully submitted,

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December 4, 2006

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