1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

7925 JONES BRANCH DRIVE
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wileyrein.com

David E. Hilliard
202.719.7058
dhilliard@wileyrein.com

John W. Kuzin
202.719.3506
jkuzin@wileyrein.com

September 3, 2008

VIA ECFS

Julius Knapp
Chief of the Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Re: *Ex Parte* Filing - 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

Dear Mr. Knapp:

Medtronic provides further support for the emissions levels proposed in its Petition for Rulemaking and the FCC's Notice of Proposed Rulemaking in the above-referenced dockets,[1] specifically the 100 µV/m at 3 m limit for emissions from 401-402 and 405-406 MHz wing band operations into the core 402-405 MHz MICS band, and the out-of-band emission limits and spurious emissions limits that apply to both bands. Moreover, as explained below, the current and proposed FCC rules are generally aligned with the ETSI standards that govern operations in these bands.

Emissions From Wing-Band Operations Into The Core 402-405 MHz MICS Band Should Be Limited To 100 µV/m at 3 m.

As Medtronic has previously explained, implantable medical devices that operate in the core band have several critical design limitations. Because implantable medical devices are limited in size and need to operate reliably for up to a decade in many cases, they must transmit at ultra-low power levels (1 - 200 nW) to conserve the

[1] *See* Medtronic Petition for Rulemaking to Amend Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz, RM-11271 (July 15, 2005); *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, ET Docket No. 06-135, 21 FCC Rcd 8164 (2006).

battery power that also supports diagnostic and therapeutic operations.[2] Indeed, to conserve battery power, MICS implantable medical devices rely upon interference avoidance mechanisms, namely Listen Before Transmit and Adaptive Frequency Agility, to help ensure that communications are successfully received the "first time."

Implantable medical device compliance with the MICS out-of-band emissions limits is achieved by a combination of ultra-low transmit power levels, body-tissue absorption, and antenna characteristics. In particular, transmissions from implantable devices are subject to approximately 30 dB of attenuation due to body tissue loss and antenna characteristics, which results in an EIRP outside the body in the range of 1 to 200 nW. The transmit power from an implantable medical device also is practically limited by the FCC's Specific Absorption Rate ("SAR") rules.

Medtronic determined that the sizeable body-tissue absorption of emissions from the implantable medical device and the already low transmit power level would sufficiently restrict the ability of these emissions to impact other core MICS band devices. Even for patients with multiple implants, tissue absorption would limit in-band interference.

In contrast to implantable device transmit power levels, which are in the 1 - 200 nW range, external devices (*e.g.*, body worn sensors) would in many cases operate at power levels near the 25 μW maximum limit. Also, the unwanted emissions proposal is different for wing band operations because patients are likely to be equipped with multiple body-worn sensors and other external transmitting devices that may be communicating at the same time.

Thus, with regard to emissions levels between the core and wing bands, the major technical consideration involves ultra-low signal levels from implantable medical

---

[2] *See* Medtronic *Ex Parte* Presentation, ET Docket No. 06-135, RM-11271 (Mar. 14, 2008) ("[I]mplantable medical devices, which have far greater battery constraints … (1) are limited in size so they can fit comfortably inside the human body; (2) must be exceedingly power efficient for the same battery is used to power therapeutic and diagnostic operations as well as wireless communications; (3) are expected to last between 5 and 10 years; and (4) can be replaced only via a surgical procedure, which introduces more risk to the patient than battery replacement in external devices.").

devices, higher-powered external medical device operations, and necessary carrier-to-interference levels to ensure simultaneous reliable communications. Recognizing the need to ensure reliable communications from ultra-low-power implantable medical devices, Medtronic proposed the 100 μV/m at 3 m limit for wing-band operations into the core band to protect implant communications. As noted below, this level is consistent with the ETSI standards.

In sum, the design constraints on core band RF implants, the expected simultaneous use of multiple higher-powered wing-band devices, and the existence of medical body area networks comprised of both core and wing band devices called for a 100 μV/m limit on emissions from wing band devices into the core MICS band.

Out-of-Band and Spurious Emissions In The 401-402 & 405-406 MHz Wing Bands and The 402-405 MHz Core Band

Medtronic also further explains the development of band edge limits in its proposed specifications for wing-band devices as compared to the established MICS regulations. *See* Proposed Rule Section 95.635(g) and 47 C.F.R. § 95.635(d).

Within the 250 kHz bands directly outside the core 402-405 MHz MICS band, emissions must be attenuated 20 dB from the maximum permitted power. Beyond those bands, the 200 μV/m at 3 m general limit applies. This allows for modulation products below the emission bandwidth to roll off without special filtering, for such filtering would be extremely difficult to incorporate in implantable medical devices.

The Petition for Rulemaking to allocate the wing bands includes similar proposals with exceptions to address the need to protect implantable medical device communications in the core band. The ultra-low-power levels from implants coupled with higher transmit power levels from body-worn and other external devices led Medtronic to propose the 100 μV/m at 3 m limit at both the 402 and 405 MHz edges inside the core band.

With regard to operations at the edges of the wing bands, the emissions limits at the 400.9 - 401.0 MHz band edge has a requirement of 20 dB down relative to the maximum permitted power (like the MICS band rules). At the upper band 406.0-406.1 MHz band edge, however, no relaxation was provided due to the presence of the EPIRB signals at 406.0-406.1 MHz. Thus, from 406 to 960 MHz, the 200 μV/m at 3 m limit would apply (increasing to 500 μV/m at 3 m above 960 MHz).

The MICS Regulations and Proposed Wing-Band Rules Governing Unwanted Emissions Are Aligned With The Corresponding ETSI Standards.

The ETSI MICS band and MEDS band standards, EN 301 839-1 and EN 302 537-1, respectively, address out-of-band emissions that fall outside the maximum operating bandwidth but within their respective operating bands by requiring attenuation of those emissions by 20 dB relative to the transmitter output power. The MICS rules and the proposed wing band rules are aligned with this ETSI requirement.

With regard to spurious emissions, the ETSI MICS band and MEDS band standards follow the general European policy that applies typically to all short range devices: that is, the ERP limit in specific critical bands is 4 nW while the ERP limit outside those bands is 250 nW or 1 μW based on frequency band.

In proposing unwanted emissions limits for the wing bands, Medtronic meant to follow the established MICS regulations that specify field strength limits based on the Section 15.209 general radiation levels, *see* 47 C.F.R. § 15.209, for spectrum just outside the band of operation. The spurious emission limit specified in Europe for the wing bands is 250 nW for emissions at and outside the combined 401 - 406 MHz band. The Petition for Rulemaking requires emissions within the 400.9 - 401.0 MHz band to be attenuated by 20 dB. Below 400.9 MHz and above 406.0 MHz, the general Section 15.209 limits of 200 μV/m at 3 m (and 500 μV/m at 3 m above 960 MHz) would apply. *See* 47 C.F.R. § 15.209.

For frequencies below 400.9 MHz and above 406.0 MHz, the FCC proposal is more stringent than the corresponding ETSI standard by approximately 11 to 13 dB. This variation in technical specifications for spurious emissions is due to the general regulatory structure for short range devices in Europe (which include medical device operations at 401-406 MHz) in lieu of the licensed service structure in the US. Thus, a device meeting the proposed U.S. standards also would satisfy the European requirements and provide an additional measure of protection.

Finally, as illustrated below, the proposed 100 μV/m limit at 3 meters in the US and 1 nW in the ETSI standard for wing-band emissions into the core MICS band devices are essentially equivalent.

A comparison of the 100 μV/m at 3 m limit versus 1 nW ERP follows:

- 1 nW = 1e-9 W radiated from a lossless half-wave dipole (ERP);

- Calculating field strength e = √(49 x 1e-9)/3 = 74.0 μV/m at 3 m, which corresponds to 37.4 dBμV/m at 3 m;

- Because both voltage and ERP are measured on an open field site, 4.9 dB is added to account for the reflected component to compare with FCC rules;

- 37.4 dBμV/m + 4.9 dBμV/m = 42.3 dBμV/m at 3 m;

- The conversion from dBμV/m to μV/m provides 130.3 μV/m at 3 m; this is within 2.3 dB of – and essentially equivalent to – the FCC proposal of 100 μV/m at 3 m.

Please do not hesitate to contact us if the Commission has any questions relating to this filing.

Sincerely,

David E. Hilliard

David E. Hilliard
John W. Kuzin

cc: Ira Keltz
Geraldine Matise
Ron Repasi
Bruce Romano
Mark Settle
Alan Stillwell
Gary Thayer