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VIA ELECTRONIC FILING

Marlene H. Dortch, Esq.
Secretary
Federal Communications Commission
Washington, DC 20554

Re: *Ex parte* Comments of Phillip Inglis – Biotronik Request for Waiver Of MICS Frequency Monitoring Requirements – ET Docket 03-92

Dear Ms. Dortch:

Medtronic files these *ex parte* comments from its technical consultant, Mr. Phillip Inglis. Mr. Inglis calls the Commission's attention to recent regulatory activity in Australia.

Specifically, the Australian Communications Authority released a medical implant communication service regulatory proposal that requires implementation of listen before transmit ("LBT") to improve the transmission reliability of medical implant communications. The Australian Authority recognizes that LBT systems provide a necessary level of reliability when sending critical medical implant data, and global harmonization of the MICS spectrum at 402-405 MHz is critical to the future success of this advanced medical service.

Please contact me with any questions or for additional information regarding this noteworthy development.

Sincerely,

/s/David E. Hilliard

David E. Hilliard
Counsel for Medtronic

cc (via email): Mr. Sam Feder, Mr. Julius Knapp, Ms. Jennifer Manner, Mr. Paul Margie, Mr. Barry Ohlson, Mr. Bruce Romano, Mr. Ed Thomas, Ms. Sheryl J. Wilkerson

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

EX PARTE COMMENTS

Medtronic, Inc., respectively submits this filing to advise the Commission of a recent international development in the ongoing establishment of a global RF band for medical implant devices and related equipment. The Australian Communications Authority ("ACA") released its regulatory proposal entitled: "Planning for Medical Implant Communications Systems (MICS) & Related Devices"[1] that requires implementation of interference mitigation techniques such as listen before transmit ("LBT"). As the ACA recognizes, the LBT protocol provides the necessary level of reliability when sending critical medical implant data by monitoring the available radio channels and choosing to transmit on the channel with the least amount of potential interference. This simple concept is a cornerstone of the Federal Communication Commission's smart radio initiative.

[1] *Planning for Medical Implant Communications Systems (MICS) & Related Devices*, Proposals Paper, Australian Communications Authority, Spectrum Planning Team, Document SPP 6/03, Oct. 2003 (hereinafter "ACA Paper") *available at* http://www.aca.gov.au/radcomm/frequency_planning/radiofrequency_planning_topics/mics.htm *last accessed* Jan. 5, 2003.

I. THE AUSTRALIAN MICS REGULATORY PROPOSAL

The Australian Communications Authority ("ACA") aimed to align its regulations with other countries' rules in order to minimize equipment costs, facilitate free trade, lessen the time-to-market for MICS equipment, and account for the practicalities associated with international travellers fitted with MICS devices. Of prime concern to the ACA was Australia's 403-405 MHz primary allocation to fixed and mobile usage and Meteorological Aids ("METAIDS") as secondary status. After examining: (1) the FCC's rules and relevant proceedings; (2) the European CEPT regulatory structure including the Harmonized Standards applicable under the R&TTE Directive for MICS devices; and (3) the ITU-R SA 1346 Recommendation for band sharing with the Meteorological Aids Service at 401-406 MHz, the ACA proposed to introduce an essentially identical regulatory arrangement. The ACA proposal may be summarized as follows:

a) Band of operation: 402 - 405 MHz.
b) Maximum EIRP: 25 µW – to apply in any 300 kHz bandwidth.
c) Operation on a no-interference basis.
d) Transmitters in implanted devices to transmit only when commanded to do so by external programmers/controllers, except when there is a medical implant event.
e) Transmitters to operate on a listen-before-transmit basis to identify and use the communication channel of lowest ambient noise.
f) Transmitters to operate with frequency agility, to enable communications on the channel with the lowest ambient noise.

A. Interference Concerns

In Australia (and several additional countries), the spectrum in which MICS is designed to operate is occupied by high power land mobile and fixed services with bandwidths that vary from 25 - 750 kHz.[2] In the U.S., in Europe, and in other countries, MICS operates in spectrum

[2] The ACA national allocation scheme for the 403-405 MHz portion of the band gives primary status to fixed and land mobile services with secondary status given to METAIDS systems. The ACA has issued 926 base station licenses in the 403-403.9875 MHz band with high power

shared on an uncoordinated and unprotected basis with meteorological services and with meteorological satellite services. Due to the heavy usage of the 403-405 MHz band by high power mobile systems, the ACA closely examined the potential for interference to MICS systems from the primary band users. Based on this interference potential and the current international operational support for MICS devices in this band, the ACA proposed "to introduce regulatory arrangements that would support the operation of MICS devices in the 402 - 405 MHz band on a no-protection no-interference basis, inline with ITU-R Recommendation SA.1346 and overseas regulatory arrangements."[3] Significantly, the ACA explained:

> [T]he existing heavy use of the sub-band 403 - 405 MHz by other services may effectively reduce the number of channels available to MICS in some areas. This is a natural consequence of the interference avoidance techniques used by MICS devices and is incorporated in their design. Allowing MICS to operate in the band 403-405 MHz where possible, provides harmonisation with international arrangements, and avoids legal technicalities that might arise from MICS devices coming into Australia from overseas and otherwise transmitting, even if only temporarily, on unauthorised frequencies.[4]

The ACA also examined one-way telemetry systems and decided against allowing such operation. The ACA reasoned:

> [T]he risk of interference to these one-way telemetry devices is significantly greater than that for MICS because of the absence of frequency agility and the associated interference avoidance techniques.
>
> **The particular one-way telemetry devices proposed for introduction into Australia, and known to be used at least in some parts of Europe, operate only on a single fixed radio communications channel that is in the heavily used mobile radio sub-band 403-403.9875 MHz in this country. This would increase substantially the likelihood**

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mobile transmitters numbering in the tens of thousands associated with these base station licenses. Typically these systems are clustered around the state capital cities. The ACA also states that some 52 licenses in the band have been issued for broadband systems with bandwidths up to 750 kHz. The sub-band 403.9875 - 405.125 MHz has some 3633 licenses issued for narrowband fixed services having 25 kHz channel bandwidths. Wideband licenses have also been issued in this band in certain rural locations.

[3] ACA Paper at 13.

[4] *Id.*

> **of unavoidable interference to the operation of these devices should they be introduced**.[5]

Two points are made clear. First, the ACA considered one-way telemetry devices to be distinct from MICS devices. Second, the ACA was concerned about interference to one-way implant transmissions and the consequent health effects of "unavoidable" interruption of the telemetry signal from implanted patients. These one-way telemetry devices obviously include the Biotronik devices that transmit at 403.6 MHz, which are the subject of the waiver request before FCC. The ACA's independent analysis showed a significant threat of signal blockage to the telemetry function of such implants, and the Authority rightly concluded that one-way, transmit-only implants should not be permitted in Australia due to the high probability of received interference.

B. MICS, Patient Mobility, And Interference

ITU-R SA.1346 Recommendation recommends that MICS systems utilize internationally compatible spectrum and employ interference mitigation techniques, as implant patients, by virtue of their mobility, will find themselves in RF environments that vary greatly, *i.e.*, environments with negligible RF ambient signals to environments similar to those in Australia where large numbers of high power mobile systems operate with primary status in the band.

As stated in the ITU-R SA.1346 Recommendation:

> Implanted medical device communications systems are inherently portable. Patients travel around the world and can be far from their primary physician when an emergency arises and the need for device communication occurs. Likewise, programmers are often moved between medical facilities and countries.[6]

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[5] *Id*. at 14.

[6] 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 ("ITU-R SA.1346") § 1.

Accordingly, patient mobility and medical necessity clearly define the need for a global band for MICS devices having common specifications.

II. PUBLIC INTEREST OBLIGATIONS

A. Interference

In establishing the MICS rules, the Federal Communications Commission "concluded that establishing a MICS would greatly improve the utility of medical implant devices by allowing physicians to establish high-speed, easy-to-use, reliable, short-range (six feet) wireless links to connect such devices with monitoring and control equipment."[7] Without reliability there can be no dependency on the transfer of critical data whether those data are diagnostic or life supporting in nature.

Because a transmit-only device (such as a Biotronik implant) cannot recognize when data are not successfully transmitted, it does not address adequately the loss of data from signal blockage from ambient signals. The repeat transmissions implemented by Biotronik do not perform this function reliably in the presence of interference such as exists in Australia or even in the U.S. home, workplace, or clinic of the American patient.[8] Indeed, repeat transmissions are a "crutch" to prop up the reliability of this one-way technology – **a crutch for one technology that needlessly pollutes the RF environment to the detriment of all users of the 402-405 MHz medical spectrum**.

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[7] *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 (1999) ¶ 3.

[8] Even if the data were transferred on a subsequent retransmission, the delay encountered could lead to injury or possibly death to the patient especially with a patient-activated (*e.g.*, emergency) message, which Biotronik's own studies show to be <u>only 65% reliable</u>. *See* n.10 *infra*.

In addition, MICS-compliant LBT systems are able avoid interference at the outset. Yet MICS-compliant systems will be subject to needless interference if they are forced to share the spectrum with non-compliant, non-LBT operations.

B. Availability of Alternative Spectrum

In its Request for Waiver, Biotronik offers no credible argument as to why its technology – having no ability to protect itself from ambient interference – must use the MICS band. Indeed, the MICS band has been internationally recognized as a valuable resource to permit reliable biomedical implant telemetry anywhere in the world on the basis that it uses smart radios that employ interference mitigation techniques. The *recommends* section of ITU-R Recommendation SA 1346 clearly notes "that interference mitigation techniques [] should be used by Medical Implant Communication Systems to protect their operation."[9]

Biotronik's technology could be made available under the provisions of Sections 15.231(e) and/or 15.209 of the Commission's rules – provisions that have been used by RF medical systems providers with one-way transmit-only devices that operate internal and/or adjacent to the body. In fact, although Biotronik uses a technology that is essentially identical to other Part 15 medical devices, it operates in the MICS band, a band designed by the Commission with specific rules to provide the necessary medical reliability.

The Biotronik technology appears to use a SAW resonator operating at or close to the design frequency of 403.6 MHz. (SAW resonator technology typically has a frequency tolerance relative to operating frequency of ±100 kHz.) Such a transmitter must be used with a receiver having a broadband input bandwidth (of the order of 500 kHz or greater) in order to account for the initial frequency tolerance plus drift due to aging over the life of the device. This technology

[9] ITU-R SA.1346.

is not at all unfamiliar, as nearly every manufacturer of a garage door opener and/or remote car entry system employs it, and shifting the transmit frequency is easily accomplished. Further, the FDA's initial acceptance of the Biotronik technology required a minimal time period of about 2 months. Thus, there is no reason, based on design requirements or FDA approval times, that Biotronik should not be required to move its one-way technology outside the MICS band.

III. CONCLUSION

In addressing the Biotronik request for a permanent waiver of the frequency monitoring requirements of MICS rules, the FCC must meet its public interest obligation. Implant patients will encounter high ambient RF environments in the U.S. and overseas where other RF services exist that will block the transmission of one-way transmit-only implant systems. By denying Biotronik's request for waiver, the agency is not precluding Biotronik's ability to market its technology under Part 15 rule sections that have been available for decades and used by other Part 15 medical devices that operate from within the human body on a transmit-only basis.

The Biotronik waiver request fails to meet the FCC's public interest obligations. Even if a limited waiver were to be granted, it would unleash a vastly inferior telemetry technology to MICS-compliant technology based on reliability that will be subject to signal blockage due to interference from various sources and run the risk of endangering the safety and well being of the implanted patient.[10] Among the known sources of interference in the 402-405 MHz band are compliant digital devices such as Class B computers, radiosondes as stated in NTIA's letter to

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[10] Biotronik's own study reported that patient-activated messages (those activated by the patient due to the patient detecting an abnormal event) were successfully transmitted in only 65% of the cases of this type of activation. Clearly, a patient with a medical implant would expect a transmission they initiate to be successfully transmitted all the time. *See The Value Of Permanent Follow-Up Of Implantable Pacemakers – First Results Of An European Trial***,** K. Wallbrück, et al., Biotronik GmbH, Technology & Service4 Center, Erlangen, German, Workshop Telemonitoring and Tele-Home-Care, Biomedizinische Technik, Band 47, Ergänzungsband 1, Teil 2, 2002.

OET, out-of-band emissions from other services, and high power land mobile systems in Australia and several other countries.

If the ACA had ignored the interference to one-way medical telemetry systems in Australia, it would be equivalent to the view that if reliability suffers because signal blockage occurs to implanted medical devices and the patient is harmed, it is a risk for the patient to assume and no one should care because chances are that such a system may work in many cases. Medtronic submits that the patient, the patient's family, and the medical community will care.

Respectfully submitted,

MEDTRONIC, INC.

By: *_/s/ Phillip M. Inglis_*
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