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April 10, 2008

John Kuzin
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VIA ELECTRONIC FILING

Marlene H. Dortch, Secretary
Federal Communications Commission
Office of the Secretary
445 12th Street, SW
Washington, DC 20554

Re: *Ex parte* Notice: 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 Ms. Dortch:

An *ex parte* meeting between representatives of Medtronic, Inc. and Commission staff occurred on April 9, 2008. Charles Farlow, Greg Haubrich, and Saurin Shah of Medtronic, Phil Inglis of TRP Inc., consultant to Medtronic, David Hilliard and the undersigned as counsel to Medtronic, met with the following members of the Commission's Office of Engineering and Technology: Julius Knapp, Ira Keltz, Geraldine Matise, Ron Repasi, Bruce Romano, Mark Settle, Alan Stillwell, and Gary Thayer.

Medtronic presented the attached materials and discussed its comments and earlier *ex parte* presentations in the above-referenced proceedings. Medtronic also noted the overwhelming support for the Commission's proposal to authorize the 401-402 and 405-406 MHz wing bands for use by body-worn and implantable medical devices.

In response to an inquiry from OET staff, Medtronic provides pin cites for each of the six conditions in the ETSI standard for ultra-low-power, low-duty-cycle operations at 403.5 - 403.8 MHz.[1] *See* footnote 1 below. The six conditions were included in previous Medtronic filings.[2]

[1] *See* ETSI EN 301 839-1 V1.2.1 (2007-04), European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods:
1. spectrum between 403.5-403.8 MHz, *see* Sections 1, 3.1, 8A, 8.1.2, 8.2.2, 8.3.2,

Please contact me with any questions concerning these matters.

Sincerely,

John W. Kuzin

John W. Kuzin

Att.

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

(Continued . . .)
& 8.6;
2. transmissions from implantable medical device only, *see* Section 8.6 ("ULP-AMI-P[eripheral] shall not use the provisions for LP/LDC");
3. 0.01 % maximum duty cycle, *see* Sections 8.3.2 & 8.6;
4. 100 nW ERP transmit power, *see* Section 8.3.2;
5. no more than 10 transmissions per hour with total transmission time less than or equal to 360 ms, *see* Section 8.6.3;
6. devices operating in the LP-LDC mode may not use the medical implant event exception, *see* Section 10A.

[2] *See* Medtronic *Ex Parte* Letters, Nov. 1, 2007, Jan. 10, 2008, and Mar. 14, 2008.

Briefing for

Federal Communications Commission

Implantable Device Telemetry and MedRadio

Medtronic

April 9, 2008

Agenda

- **Introduction**
  - Implantable Device Telemetry Considerations
- **Medical Implant Communications Service (MICS)**
  - Review
  - Worldwide Status
- **Medical Data Service (MEDS) European Status**
- **Medtronic's Position on Voice Communication (MICS & MEDS)**
- **AdvaMed's Position on Voice Communication (MICS & MEDS)**
- **Voice Communication Options**
- **Medtronic's Position on DexCom's Waiver**
- **Summary**
- **Questions**

Implantable Device Telemetry Considerations

- **Implantable cardiac defibrillator and pacemaker devices with small primary batteries must last 5 to 10 years**
  - Ultra low power telemetry is required to achieve this longevity
  - Telemetry is a very small percentage of the overall power supply budget
- **Telemetry range in excess of 2 meters is desired**
  - This rules out inductively coupled telemetry
- **Frequency band selection**
  - Frequency bands with minimal interference should be used
  - Interference mitigation techniques are required to support reliable medical communications, including real-time medical data
  - Worldwide frequency band allocation and international compatibility is critical
  - Frequencies must support efficient propagation out of the body
- **Support for life-critical applications**

MICS Review
Usage Scenarios

- **Summary of MICS usage scenarios**

Implant

- Streamlined implant procedure
- Removes the inductive antenna from the sterile field
- Real-time communication of critical data

In-office

- Complete wireless follow-up with Leadless Electrocardiogram (ECG)
- Improved comfort for patient

Remote

- Pre-scheduled device checks
- Replaces regularly scheduled clinic visits
- Physician selected alert conditions

MICS Worldwide Status
Medtronic Product Deployment

- **In 2002, the FCC approved Medtronic MICS programmer/controllers**
  - Now fielded in cardiology centers worldwide
- **On May 17, 2006, the FDA approved Concerto™ (CRT-D) and Virtuoso™ (ICD) with Conexus™ Wireless Telemetry**
  - July 26, 2007 (ex parte): over 40,000 implants worldwide
  - Today: over 100,000 implants worldwide

Implantable Device Development and Deployment Cycle

- **Example: pacemaker, implantable cardiac defibrillators**

Product/Therapy Development (FCC MICS band radio integration)	=	2 – 3 Years
FDA Regulatory Approvals (Therapy safety/efficacy clinical studies)	=	1.75 – 3 Years
Device Longevity	=	5 – 10 Years
TOTAL		8.75 – 16 Years

MICS Worldwide Status
Implantable Device Proliferation

- **St. Jude Medical's Current ™ DR RF Module 2207 FCC submission; FCC ID RIASJMRF – part of an LBT/AFA compliant system**

Intertek ETL SEMKO

ST. JUDE MEDICAL

Dok.nr. / Doc.No.	Utg. / Rev.	Sida / Page
50019818	1	1(7)

Dokumentnamn / Title: Specific Absorption Rate (SAR) Analysis for device Current DR RF - Model 2207		
Avdelning / Dept.: Ut	Utfärdare / Originator: Tomas Snitting	Ersätter / Supersedes: N/A
Avser / Concerns: Unity	Säkerhetsklass / Classification: **internal**	Bilagor / Attachments: N/A
Distribueras till / Distribution list: N/A		

Utgåva / Revision	Revisionshistoria / Revisions History
001	First Revision

1 Introduction

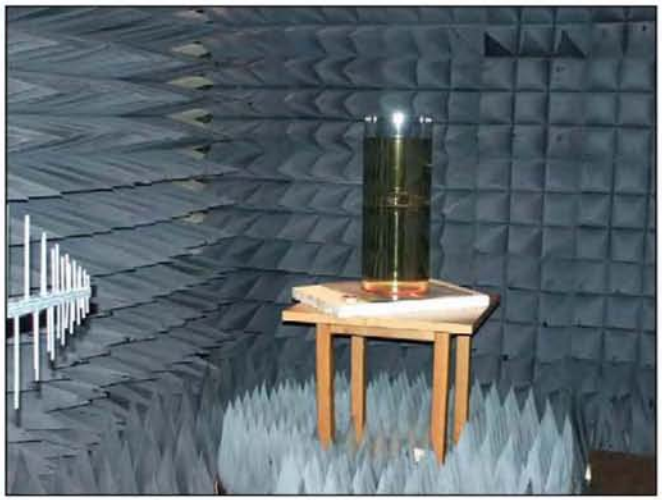
St. Jude Medical has developed a wireless communication system that is operating under the MICS (Medical Implant Communication Service) standard. The intended use is for communication between Implanted Medical Devices (IMD) and an, to the body, external transceiver. Wireless communication will provide communication at much higher speed and longer distance as compared to the present inductive communication. The IMD is using a loop antenna mounted on the header. This report covers the *Current DR RF - Model 2207*. According to 47 CFR Part 95, section 95.603(f) a simulation shall be performed to calculate SAR values. This in order to show compliance to radio frequency exposure limits as defined in, 47 CFR Part1, section 1.1307 and in 47 CFR Part2, section 2.1903. The usage of the equipment is uncontrolled and hence the limit for partial-body SAR is 1.6W/kg. The partial-body SAR is averaged over any 1g tissue volume in the shape of a cube. The Whole-body limit for average SAR is 0.08W/kg.

2 Scope

The scope of this report is to show compliance of device *Current DR RF - Model 2207*, as required in 47 CFR Part 95, section 95.603(f).

MICS Worldwide Status
Implantable Device Proliferation

- **Biotronik's Tach 35 (4120) Implantable Cardioverter Defibrillator (ICD) submission; FCC ID QRILUMAXT – part of an LBT/AFA compliant system**



ELECTRONIC TECHNOLOGY SYSTEMS DR. GENZ GMBH

Applicant: BIOTRONIK GmbH & Co. KG FCC ID: QRILUMAXT

BIOTRONIK	Technical Report *Tach 35 (4120) SAR Analysis*		3146179 Rev. A Page 1 of 11
Letter	**Revisions**	**Date**	**Approval**
A	Original	02-23-2006	BPS

1 Purpose

The purpose of this report is to document the Specific Absorption Rate (SAR) computational analysis of the Biotronik Tach 35 (4120) Implantable Cardioverter Defibrillator (ICD).

2 Conclusion

The Tach 35 ICD, employing an ultra-low power RF transmitter, complies with the SAR regulatory limits specified in 47 CFR 95.603, §2.1093, and §1.1310. The Tach 35 maximum worst-case, time-averaged SAR is **25.417 microW/kg**, averaged over 1 gram of tissue. The regulatory limit specified in 47 CFR 2.1093 is **1.6 Watts/kg**, averaged over 1 gram of tissue. As such, the Tach 35 SAR is **48 dB** below the maximum allowable regulatory limit specified by the FCC.

3 Applicability

This report is applicable to all Tach 35 ICD's that use the same MICS RF transmitter circuitry and antenna structure noted in this report.

4 Document History

Ver. A 02-23-2006 Initial Release

5 References

47 CFR 95.603 Certification Required
47 CFR 2.1093 Radio Frequency Radiation Exposure Evaluation: Portable Devices
47 CFR 1.1310 Radio Frequency Radiation Exposure Limits.

MICS Worldwide Status
Implantable Device Proliferation

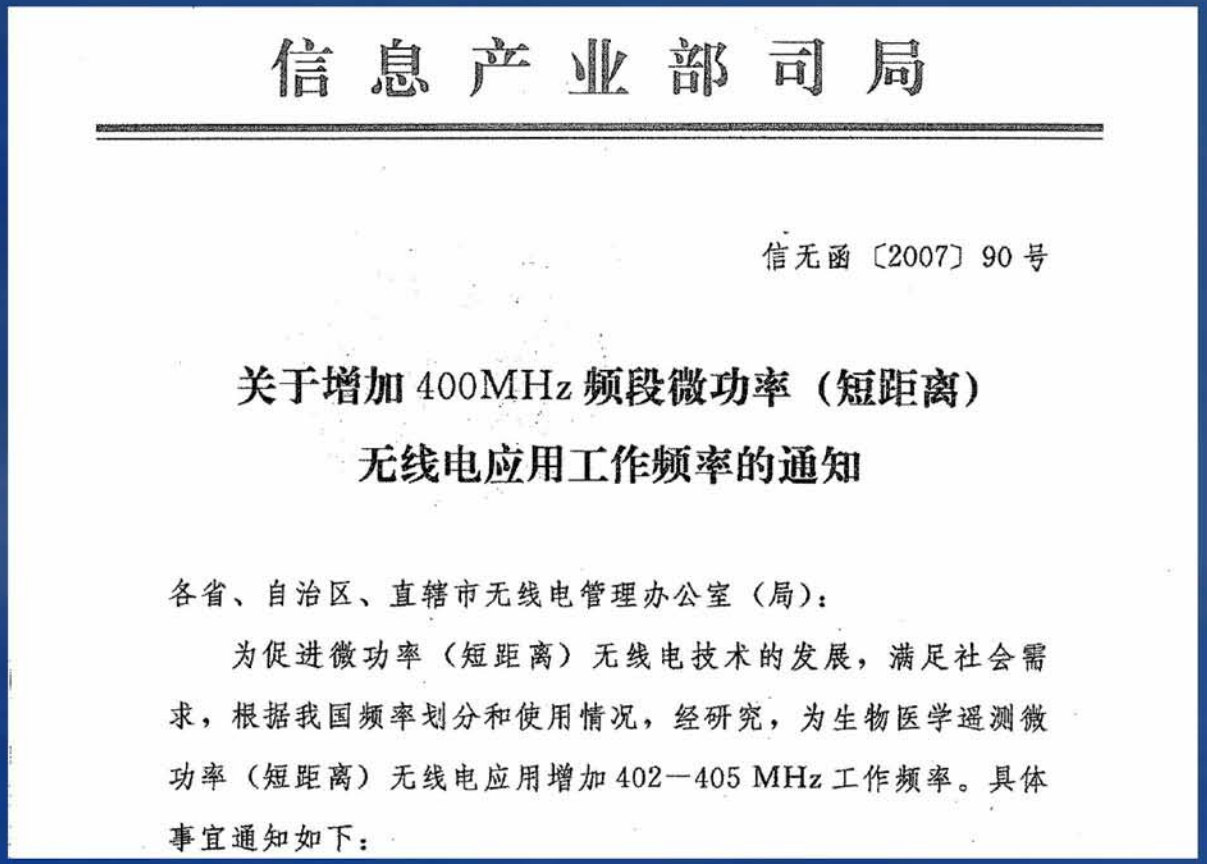
- **Proliferation of MICS band devices is expected to accelerate as infrastructure (e.g., MICS programmers/controllers) continues to be established throughout the world**
  - Infrastructure cost is significant for all manufacturers; investments in external instruments need to be leveraged for several years

Medtronic 2490C
CareLink® Monitor

Medtronic 2090W
CareLink® Programmer

MICS Worldwide Status
Implantable Device Proliferation

- **Widespread adoption of the MICS band continues**
  - Over fifty-five countries worldwide
  - MICS regulations in China were adopted on October 12, 2007
    - Aligned with existing FCC MICS rules and ETSI standard (e.g., LBT)



信 息 产 业 部 司 局

信无函〔2007〕90 号

关于增加 400MHz 频段微功率（短距离）无线电应用工作频率的通知

各省、自治区、直辖市无线电管理办公室（局）：

为促进微功率（短距离）无线电技术的发展，满足社会需求，根据我国频率划分和使用情况，经研究，为生物医学遥测微功率（短距离）无线电应用增加 402—405 MHz 工作频率。具体事宜通知如下：

MEDS European Status

- **MEDS frequency bands are fully approved**
  - ERC/REC 70-03, Annex 12, a1 and a2 (Feb. 28, 2008 version shown)

Regulatory parameters related to Annex 12

	Frequency Band	Power/Magnetic Field	Duty cycle	Channel spacing	ECC/ERC Decision	Notes
a	402-405 MHz	25 µW e.r.p.	No Restriction	25 kHz	ERC/DEC/(01)17	For Ultra Low Power Active Medical Implants covered by the applicable harmonised standard. Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz.
a1	401-402 MHz	25 µW e.r.p.	No Restriction for devices with LBT, otherwise ≤0.1% (see note 2)	25 kHz		For Ultra Low Power Active Medical Implants and accessories covered by the applicable harmonised standard and not covered by band a. Individual transmitters may combine adjacent 25 kHz channels for increased bandwidth up to 100 kHz (see note 1).
a2	405-406 MHz	25 µW e.r.p.	No Restriction for devices with LBT, otherwise ≤0.1% (see note 2)	25 kHz		For Ultra Low Power Active Medical Implants and accessories covered by the applicable harmonised standard and not covered by band a. Individual transmitters may combine adjacent 25 kHz channels for increased bandwidth up to 100 kHz (see note 1).

Note 1: Due to the limited available spectrum of 1 MHz, a maximum bandwidth of 100 kHz is proposed for these bands to ensure that several users could access the band concurrently.

Note 2: Systems not providing frequency agility based on ambient RF field sensing, be limited to a maximum permitted e.r.p. of 250 nanowatts with a duty cycle of ≤ 0.1%.

MEDS European Status

- **The MEDS ETSI standard European vote closed on December 15, 2007**
  - The result of the vote ended with 100% approval for all EU+EFTA countries

ETSI EN 302 537-1 V1.1.2 (2007-12)

European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods

Medtronic's Position on Voice Communication (MICS & MEDS)

- Permitting wireless hearing aid, high duty-cycle operations in any portion of the MedRadio band would render it useless for non-voice wireless medical devices supporting important diagnostic, therapeutic and monitoring functions
- Increasing spectrum demands for non-voice implantable and body-worn devices as they continue to proliferate
- Implantable device applications have unique requirements

AdvaMed's Position on Voice Communication (MICS & MEDS)

- **In AdvaMed's MedRadio Reply Comments, members of the medical device industry agreed voice should be prohibited in the core and wing bands**

> 2. The existing MICS band rules prohibiting the transmission of voice (i.e., 95.631(h)) should be maintained for the core and wing bands.

Excerpt of AdvaMed's Reply Comments filed with the FCC on December 4, 2006

- **There is industry consensus**
  - Existing MICS band rules prohibiting voice should be maintained
  - Voice should also be prohibited in the MEDS (i.e., "wing" bands)

Voice Communication Options

- **Hearing aids can and should be accommodated in other bands**
  - Recognizing this issue, FCC MICS and proposed MEDS regulations and international standards are limited to non-voice applications
    - AMI Semiconductor's proposal is not aligned with the existing ETSI MEDS standard (EN 302 537-1, -2)
  - There are several other spectrum options for wireless hearing aid applications, such as under Part 15, LPRS, 169 MHz in Europe, Bluetooth, and inductive systems

Medtronic's Position on DexCom's Waiver

- **DexCom's need for a waiver at the full 25 uW MICS radiated power level is not proven:**
  - The analysis presented by DexCom shows an exceedingly poor receiver design having a noise figure >22 dB
  - Implantable device manufacturers achieve greater range with much lower transmit power (~1 nW to 250 nW EIRP)
  - Poor system design should not be a basis for a rule change
- **25 uW non-LBT devices will interfere with MICS sessions as increased utilization of the MICS band occurs**
- **To minimize impact to existing and future users of the MICS band, non-LBT devices should utilize the MEDS band which is ideally suited for this type of system**

Summary

- **Existing Part 95 MICS rules should be affirmed**
  - To ensure sharing of the band with the primary user, Meteorological Aids (i.e., ITU-R SA.1346)
  - Listen Before Transmit/Least Interfered Channel spectrum access and Adaptive Frequency Agility techniques have been proven effective for establishing high reliability communication links
  - International harmonization; regulations with the same basic parameters have been adopted in all major regions of the world
  - The unique usage scenarios supported by MICS

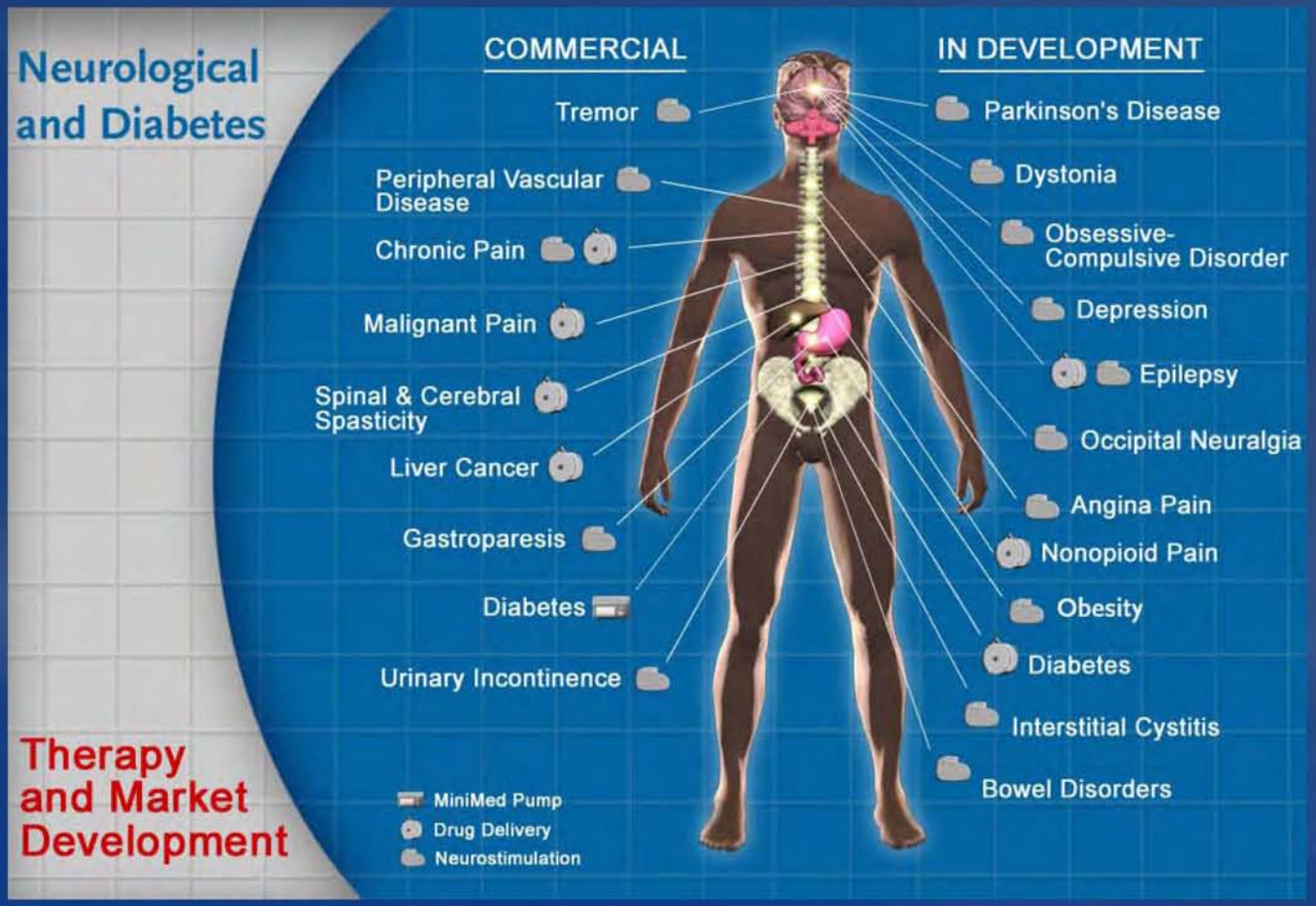
The medical device industry, physicians, and patients expect MICS to remain a high reliability service requiring the interference mitigation mechanisms recommended by ITU-R SA.1346

Summary

- **MEDS accommodates the medical need for external-to-external device communication and multiple, low-cost, transmit only sensors**
  - Many systems (e.g., drug delivery) require external-to-external device communication
  - Sensors have extreme size constraints; in some cases, transmit only technology may be the only feasible option

MICS and MEDS are different, but complementary, band allocations

Summary & Questions



Wireless medical devices will continue to proliferate