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September 5, 2003

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VIA ECFS

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

Re: ET Docket 03-92
Ex Parte Notification

Dear Ms. Dortch:

On September 4, 2003, Andrina Hougham, Steve Goedeke, Len Twetan, Greg Haubrich and Javaid Masoud from Medtronic, Inc., accompanied by Robert Pettit, David Hilliard, and John Kuzin from Wiley Rein & Fielding LLP, and Philip Inglis of TRP, Inc., presented to Commission staff a demonstration of Listen Before Transmit ("LBT") technology for use in Medical Implant Communications Systems. The following FCC personnel attended the presentation: Ed Thomas, Julius Knapp, James Schlichting, Bruce Romano, Alan Scrimie, Ira Keltz, Hugh Van Tuyl of the Office of Engineering and Technology, and Herb Zeiler of the Wireless Telecommunications Bureau.

A copy of the presentation shown at the meeting is attached.

Respectfully,

/s/ David E. Hilliard

David E. Hilliard
Counsel for Medtronic

Attachment

cc (via email): Messrs. Thomas, Knapp, Schlichting, Romano, Keltz,
Van Tuyl, and Zeiler

The FCC's MICS Rules

September 4, 2003

1



Medtronic
When Life Depends on Medical Technology

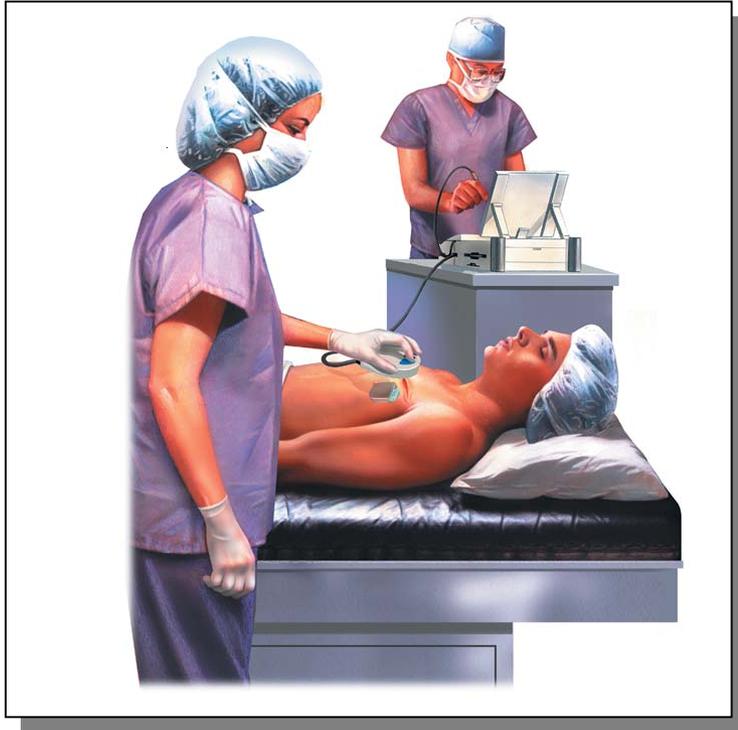
Why MICS?

- ❖ The FCC recognized and responded to the need for systems capable of communicating implanted medical device's life critical data with very high reliability over a range of several meters.

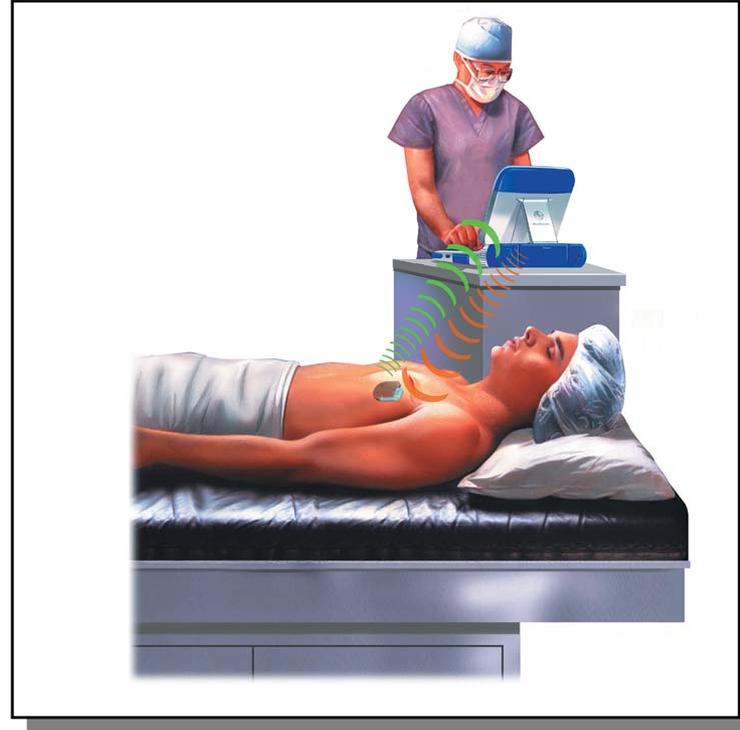


At Implant

Without MICS



With MICS

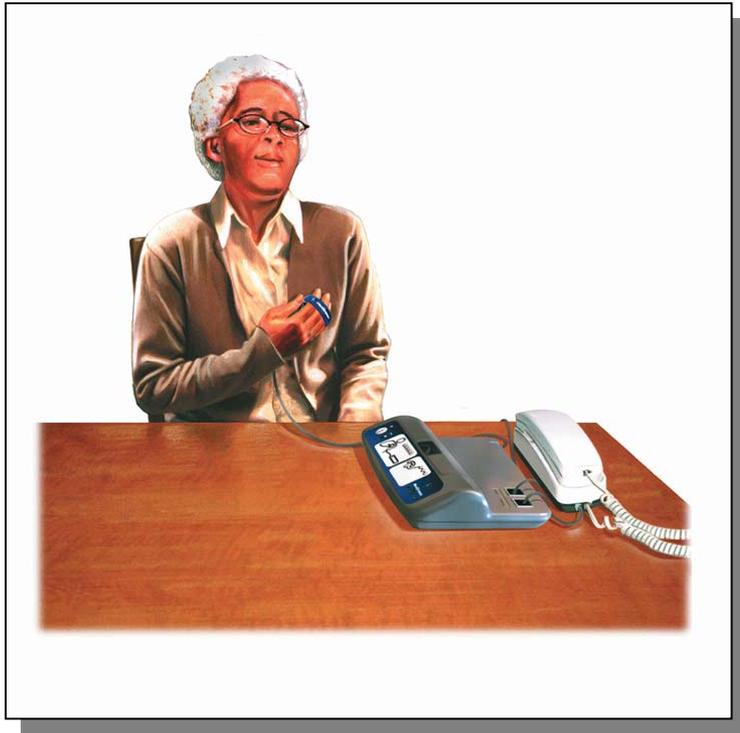


- ❖ Removes programming head from sterile field
- ❖ Maintains telemetry throughout procedure



Home Monitoring

Without MICS



With MICS

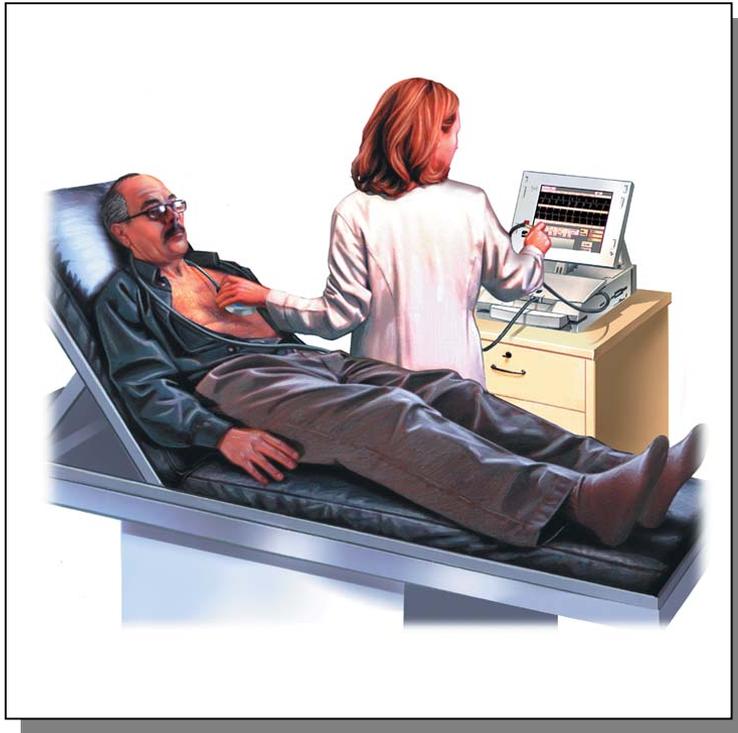


- ❖ Dramatically improves compliance and thus patient outcomes
- ❖ Creates a safety net under those in need

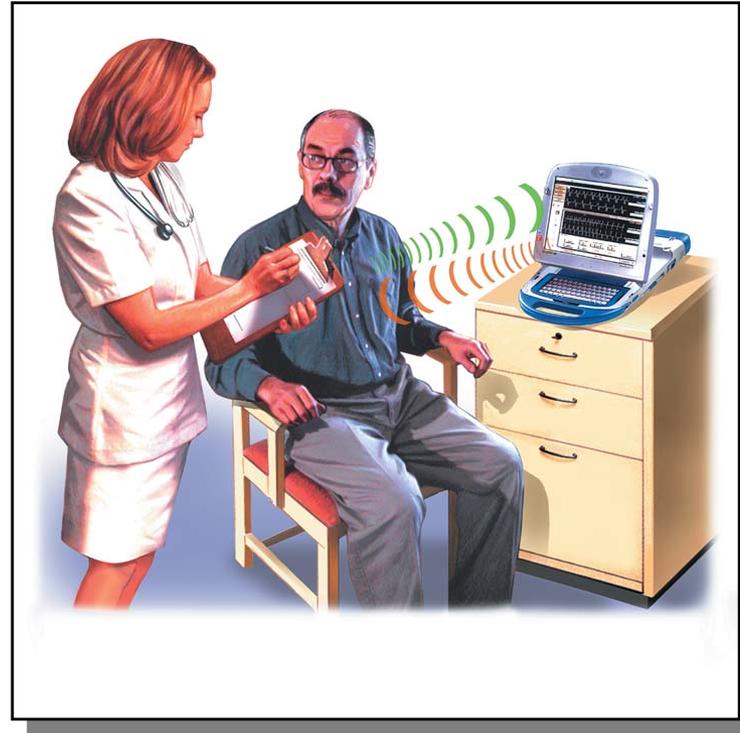


In-Clinic Follow-Up

Without MICS



With MICS



- ❖ Patient's personal space is not violated
- ❖ No need to place programming head on tender tissue
- ❖ Improves clinic efficiency



MICS Band History

- Began discussions with the FCC (OET) July of 1995
- Once Metaids option was identified, vetted concept with FCC / NTIA / NWS / Air Force / NOAA / WMO
- Ultimately gained support from Primary users
- Successfully followed the ITU-R process resulting in formal recommendation
- Petition for Rulemaking filed July 1997
- NPRM issued February 1999
- FCC issued Report and Order November 1999
 - Rules include LBT to avoid interference



From the Report and Order

The FCC 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”

MICS 1999 Report & Order at ¶ 3.

- ❖ Clearly, the FCC recognized and valued the critical reliability aspects of MICS



Typical medical community comment

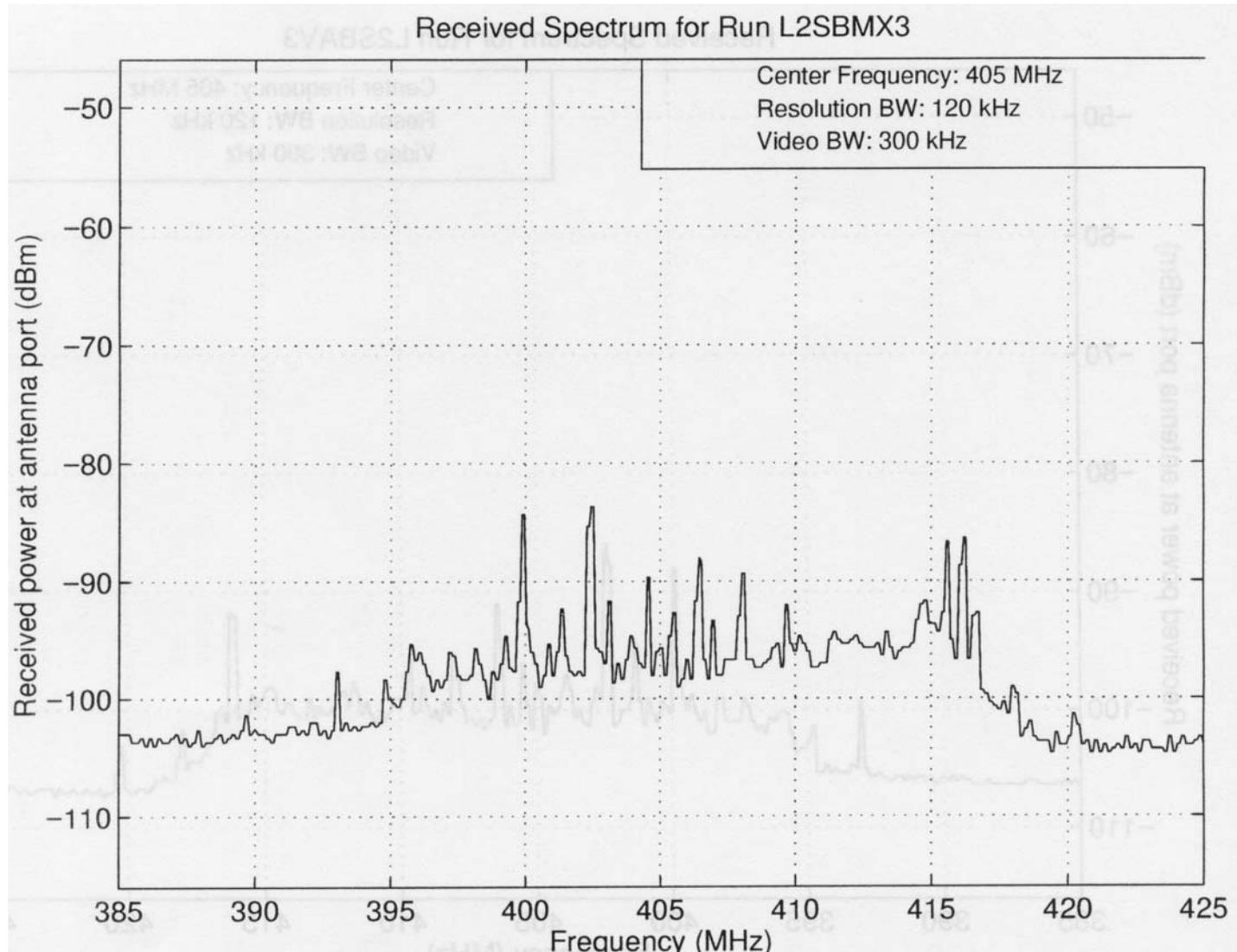
- ❖ Rick Pollack – Executive Vice President American Hospital Association

“We believe that this [MICS] is an important step in minimizing electromagnetic interference (EMI) from other users of the spectrum, which could negatively impact patient safety.”

- ❖ The medical community also recognizes the need for MICS to be of high reliability



Typical Interference (hospital)

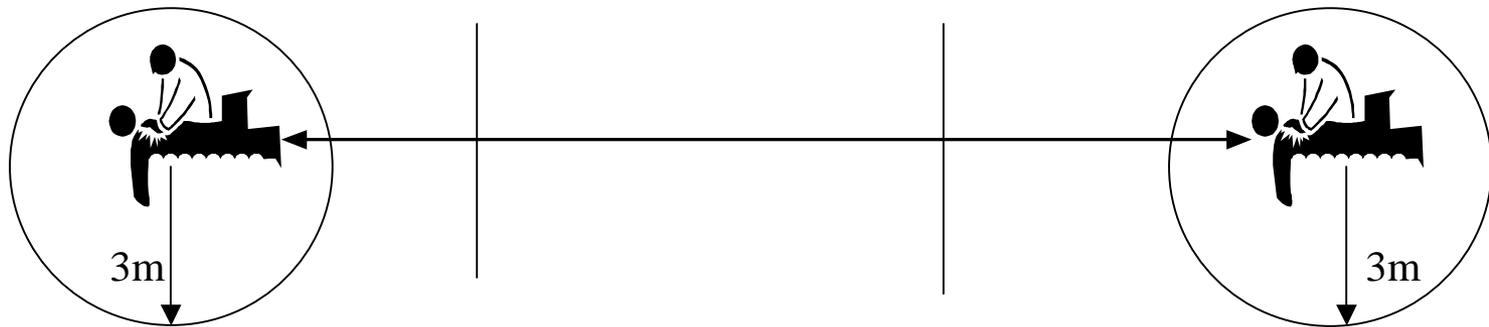


MICS to MICS Interference

❖ VICTIM RECEIVER ON CIRCLE CIRCUMFERENCE

MICS Compliant Device

Transmit only Device



Interference can occur to Programmer, remote monitor, or implant Receiver

Wall Large D

Wall Large D

Interference can occur only to remote monitor Receiver.

Range of interference is 18 to 170m



Interference Calculations

Assumptions: C/I ratio 14 dB, Concurrent co-channel operation at specified power level.

	Device and F/S level			No interference	100% Probability of interference	Geographic Area coverage Probability of interference <1% to 100%	Interference to whom by whom
	MICS Implant	Transmit only Implant	Programmer/Monitor (MICS)	Patient Separation Distance	Patient Separation Distance		
Case 1 Equal F/S levels from all 3 devices	? Compliant level is assumed	? Compliant level is assumed	? Compliant level is assumed	>18m	< 12 m	1000 m ² or >30m x 30 m	Mutual Interference between each system
Case 2 Assume two intervening walls, 12 dB attenuation each	100 uV/m @ 3m	100 uV/m @ 3m	18 mV/m @ 3m	>170	<164	80,000 m ² or > 280m x 280m	Interference to transmit only system from MICS programmer/monitor or
Case 3 Assume two intervening walls as above	100 uV/m @ 3m	18 mV/m @ 3m	18 mV/m @ 3m	>170	<164	80,000 m ² or > 280m x 280m	Interference to MICS System from Transmit only implant
Case 4 Assume two intervening walls as above	18 mV/m @ 3m	100 uV/m	18 mV/m @ 3m	>170	<164	80,000 m ² or > 280m x 280m	Interference to transmit only system from MICS Programmer and/or implant

100% probability of interference occurs when the patient spacing is such that the required no interference separation distance between the interfering transmitter and the victim receiver cannot be achieved under any circumstances.



- ❖ Smart technology – an intelligent system with awareness of other users.
 - ♦ Avoids disrupting sessions underway – thereby protecting patient safety
 - ♦ MICS supports multiple users and interference avoidance creating the safe, reliable system intended by the regulations.

- ❖ Listen Before Transmit is the key attribute of this self-regulating, reliable system.



MICS Commercialization Status

- ❖ Medtronic is coming to market
 - ◆ Device testing (implant and programmer) complete
 - ◆ Programmer certification granted
 - ◆ Implant request for certification filed
- ❖ Major U.S. medical implantable device manufacturers (>98% of the market) have MICS products in development.
- ❖ There are now commercially available MICS solutions. Vendors include:
 - ◆ AMI Semiconductor
 - ◆ RF Monolithic
 - ◆ RFMD
 - ◆ Others



Conclusions

- ❖ Life critical medical implant communication systems must be reliable.
- ❖ Without LBT, safe separation distances to prevent interference cannot be maintained in the expected operating environments and thus compromise patient safety
- ❖ LBT is needed to eliminate the “very real” risk of METAIDS to MICS interference
- ❖ The self regulating MICS rules were “built to last” and dramatically improve healthcare.

