



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

Virginia Office
7925 JONES BRANCH DRIVE
SUITE 6200
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wrf.com

July 27, 2007

John W. Kuzin
202.719.3506
jkuzin@wrf.com

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 July 26, 2007. Charles Farlow and Saurin Shah of Medtronic, Phil Inglis of TRP Inc., consultant to Medtronic, David Hilliard and the undersigned as counsel to Medtronic, Inc., met with the following members of the Commission’s Office of Engineering and Technology: Julius Knapp, Geraldine Matise, Bruce Romano, and Gary Thayer.

Medtronic presented the attached materials and discussed Medtronic’s comments in the above-referenced proceedings, noting 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. Medtronic stressed the need to maintain: (i) the spectrum access protocol in core 402-405 MHz band; and (ii) the current limitations in the core band for communications between implantable medical devices and associated programmer/controller peripheral equipment.

Please contact me with any questions concerning this matter.

Sincerely,

/s/ John W. Kuzin

John W. Kuzin

Att.

cc: Julius Knapp
Geraldine Matise
Bruce Romano
Gary Thayer

Briefing for
Federal Communications Commission

**Medical Implant Communications Service (MICS)
and the MedRadio Proceeding**

Medtronic
July 26, 2007



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Agenda

- **Introduction**
- **Medical Implant Communications Service (MICS)**
 - Review
 - Worldwide Status
 - Summary
- **Medical Data Service (MEDS)**
 - Review
 - European Status
- **FCC MedRadio Proceeding**
 - Interference Mitigation
 - Body-worn Devices
- **Summary**
- **Questions**



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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

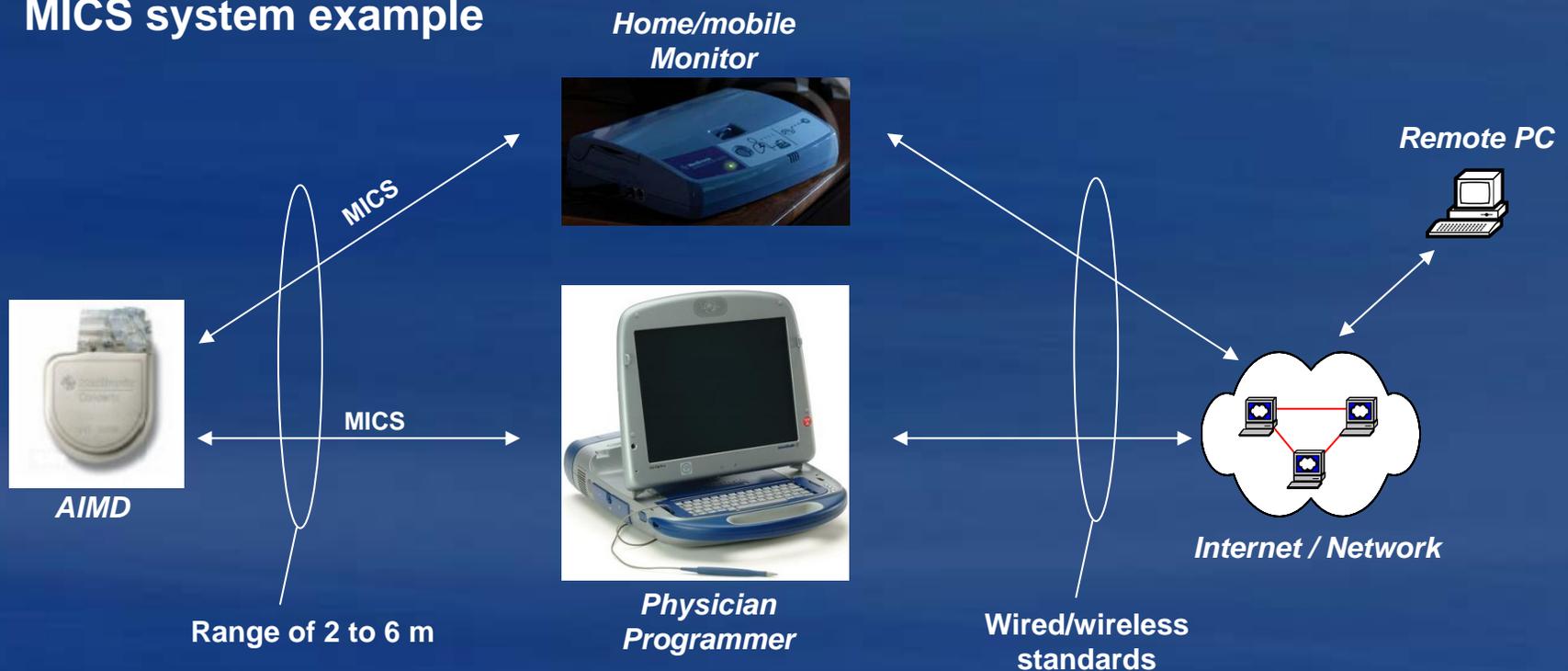


Remote

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

MICS Review System Example

- MICS system example



MICS – short-range, reliable, time-critical communications between implant and external peripherals in both medical facilities and elsewhere

MICS Review

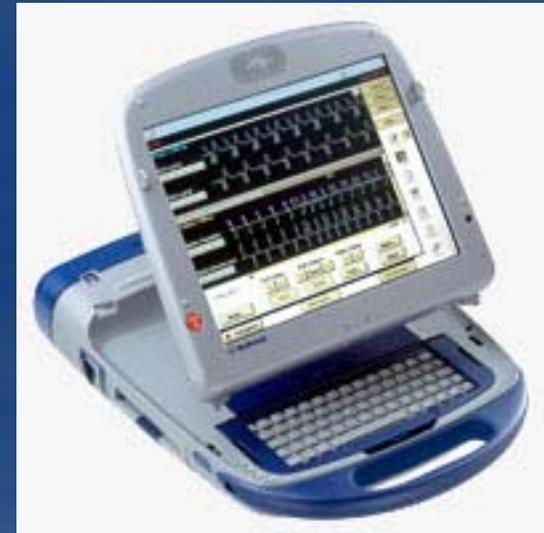
Scenarios Requiring Time Critical Telemetry

- **Detection of life-threatening conditions or precursors**
 - Precursors to ventricular fibrillation: ventricular tachycardia, frequent premature ventricular contractions (PVC)
 - Precursors to stroke: transient ischemic attack (TIA), etc.
 - Detection of reduced blood oxygen, high blood pressure, previously undiagnosed arrhythmias, etc.
- **Change or reduction in therapy efficacy**
 - Increased frequency of anti-tachycardia pacing (ATP) to restore normal heart rhythm
 - Lead dislodgement or fracture (e.g., due to patient overexertion or trauma)
- **Patient initiated therapy**
 - Seizure management (e.g., epilepsy)
 - Pain control (via drug delivery or electrical stimulation)

MICS Review

Real-time Telemetry

- Long duration interference events can cause noticeable interruption of real-time data transfer
- The latency requirements for real-time communications limit the practical retransmission capability of MICS systems
 - Transmission latency of >200 msec can create problems because physicians often correlate the electrogram (EGM) uplink (from an implantable device) with the surface electrocardiogram (ECG)



Real-time EGM display from an implantable device

Latency and retransmission capability are closely interrelated



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MICS Worldwide Status

Medtronic Product Deployment

- **Medtronic's distance telemetry solution utilizes the Medical Implant Communications Service (MICS) band at 402-405 MHz**
 - Regulations/standards approved in major regions (e.g., US, Europe, Canada, Australia, Japan)
 - Medtronic's MICS products fully comply with existing FCC MICS rules
- **In 2002, the FCC approved Medtronic MICS programmer/controllers**
 - Now fielded in cardiology centers throughout US
- **On May 17, 2006, the FDA approved Concerto™ (CRT-D) and Virtuoso™ (ICD) with Conexus™ Wireless Telemetry**
 - Over 40,000 implants worldwide



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MICS Worldwide Status

New Markets

- Medtronic MICS products are being launched in new markets
 - MICS regulations in Japan were adopted on August 8, 2005
 - Commercial launch of Concerto™ (CRT-D) and Virtuoso™ (ICD) in Japan on July 6, 2007



*(excerpt
of press
release)*

News Release

Medtronic Media Contacts:

[Jeff Warren](#), Investor Relations, 763-505-2896

[Tracy McNulty](#), Public Relations, 763-514-4553

[Yvan Deurbroeck](#), Public Relations, (+41 21) 802-7574

[Masumi Iwama](#), Public Relations & Government Affairs, 81-44-540-6438

Medtronic Launches First Wireless Devices in Japan

Concerto® CRT-D and Virtuoso® ICD Now Available for Japanese Patients

MINNEAPOLIS AND TOKYO – July 6, 2007 – Medtronic, Inc. (NYSE: MDT) announced the commercial launch of its latest cardiac resynchronization therapy-defibrillator, the Concerto® CRT-D, and its latest implantable cardioverter-defibrillator, the Virtuoso® ICD. Both devices are the first of their kind in Japan equipped with key features, including wireless telemetry.

ICDs are implanted medical devices used to detect sudden, potentially fatal arrhythmias and automatically deliver therapies to restore the normal rhythm of the heart. CRT-D devices are equipped with the functions of an ICD while also providing cardiac resynchronization therapy for patients suffering from heart failure, in which the left and right ventricles (lower chambers) of the heart fail to provide a synchronized beat. In addition to the above functions, the Concerto and Virtuoso are the first devices in Japan with three new features.

Wireless Functionality Reduces Time Needed for Follow-Ups and Procedures

Implanted devices such as pacemakers and ICDs are capable of internally recording the patient's pulse, device therapies delivered, and other similar data over a certain period of time. This information is then obtained by the patient's doctor during in-office follow-up visits every three to four months and used to determine the patient's subsequent treatment and therapies. Conventional devices require an in-office visit where a reader is placed over the implanted device to allow for transfer of this data; the Concerto and Virtuoso provide this information wirelessly, precluding the need for patients to disrobe. Changes to certain device settings can also be performed using the wireless function. Additionally, the initial settings programmed during device implant can be performed wirelessly, avoiding the placement of the programming head in the sterile field ordinarily used for this function, thereby potentially reducing the time for surgical procedures.

MICS Summary

- **MICS accommodates the medical need for highly reliable, time critical communications between implanted medical devices and external peripherals**
 - Allows simultaneous MICS communication sessions
 - Enables interactive home healthcare for patients
 - Enhances safety and efficiency
 - Facilitates improved medical implant follow-up procedures
- **Widespread adoption of the MICS band continues**
 - Over fifty countries worldwide
- **St. Jude Medical and Biotronik received FCC grants for MICS compliant systems performing Listen Before Talk (LBT) and Adaptive Frequency Agility (AFA)**



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MEDS Review Introduction

- **Medical Data Service (MEDS)**
 - 401-402/405-406 MHz
 - ETSI released TR 102 343 (V1.1.1) in July 2004

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**

- Medtronic filed a Petition for Rulemaking to the FCC on July 15, 2005 (RM-11271)
- Provides a band to support emerging applications such as body area networks (BAN) and insulin pump/sensor/controller communication



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MEDS Review System Example

- **Diabetes external-to-external applications**

- Remote control to insulin pump

- Remote control generates short transmissions with commands for bolus, suspend and activate insulin pump



- Insulin pump to personal computer RF adapter

- Sequence of transmissions between the devices to download pump/monitor history data



MEDS Review

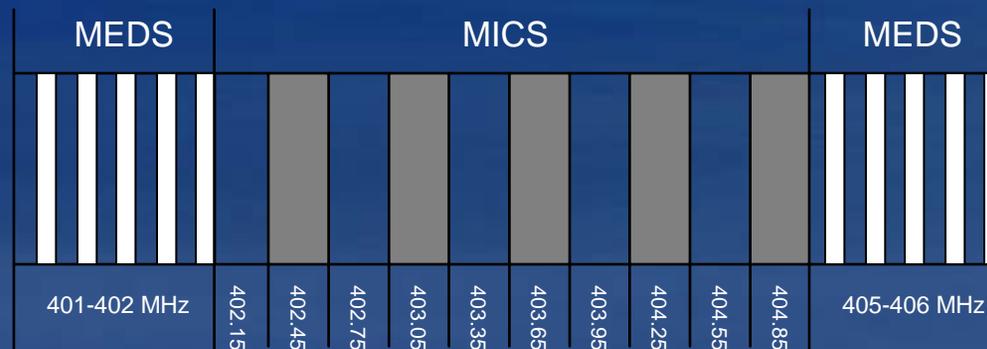
Comparison between MICS and MEDS

Frequency	402 - 405 MHz	401 - 402 and 405 - 406 MHz
Maximum Emission Bandwidth	300 kHz	100 kHz
Maximum Frequency Tolerance	+/- 100 ppm	
Maximum Radiated Transmit Power	25 microwatts (EIRP)	
Listen Before Talk/Least Interfered Channel Spectrum Access?	Yes	Yes
Transmit only, Low Power Low Duty Cycle (LPLDC) Communication?	No	Yes
Approval Status	Approved US, EU, Canada, Japan, Australia and elsewhere (>50 countries)	Frequency band approved in EU; pending approval elsewhere
Between Implantable Devices?	Yes	
Between Implantable Device and External Medical Instruments?	Yes, with programmer/controller	Yes
Between External Medical Instruments?	No	Yes
	MICS (Medical Implant Communications Service)	MEDS (Medical Data Service)

MEDS Review Frequency Plan

- **Medtronic MEDS frequency plan**

- 10 channels on each side of the MICS band, spaced at 100 kHz (i.e., the center frequency of the first MEDS channel is 401.05 MHz)



- **MEDS emissions limits into the MICS band have been specified to mitigate a potential “near/far problem”**

- That is, body-worn MEDS transmitters interfering with transmissions from distant MICS programmer/controllers

MEDS European Status

- MEDS frequency bands are fully approved
 - ERC/REC 70-03, Annex 12, bands a1 and a2

Regulatory parameters related to Annex 12

	Frequency Band	Power/Magnetic Field	Duty cycle	Channel spacing	ECC/ERC Decision	Notes
a	402 - 405 MHz	25 μ W 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 μ W e.r.p.	No Restriction for devices with LBT, otherwise $\leq 0,1\%$ (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 μ W e.r.p.	No Restriction for devices with LBT, otherwise $\leq 0,1\%$ (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).



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MEDS European Status

- **MEDS standard is in the final stage (National Voting)**
 - European standard (Draft ETSI EN 302 537-1,-2) Public Enquiry phase closed April 6, 2007
 - Comment resolution meeting completed on June 1, 2007
 - Estimated EU Official Journal publication in November 2007

Draft **ETSI EN 302 537-1**v.0.0.3 (2006-010)

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 – 402 MHz and 405 – 406 MHz;
Part 1: Technical characteristics and test methods**



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FCC MedRadio Proceeding Interference Mitigation

- **Why are LBT and AFA so critical?**
- **Interference avoidance is needed to support reliable medical communications, including real-time medical data**
 - Other MICS users
 - Meteorological Aids (i.e., ITU-R SA.1346)
 - Unintentional emitters, other sources of radio noise
- **Interference reduction - to other MICS users; e.g., spectrum sharing**
- **Eliminates/reduces retransmissions and channel switching**
 - Impacts battery life



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FCC MedRadio Proceeding Interference Mitigation

- **Meteorological Aids (i.e., ITU-R SA.1346)**
 - “These [MICS] channels are used to avoid interferers and support the simultaneous operation of multiple devices in the same area (such as clinics with multiple rooms). International spectrum studies have shown that even with 3 MHz available only one or two channels [in the core band] will be usable in many environments.”
- **The interference environment in hospitals/clinics is dynamic and challenging**
 - Medtronic contracted Wireless Valley Communications (Dr. Theodore S. Rappaport) to conduct an extensive noise study in the 400 MHz band during 1995-1996 (before MICS was proposed)
 - Smart radio techniques (i.e., LBT and AFA) are essential



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FCC MedRadio Proceeding Interference Mitigation

- One commenter noted that the 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. See Cleveland FES Center Comments.
- “[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)” GE Healthcare Comments at 7.
- 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. See NDI Medical Comments.



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FCC MedRadio Proceeding Interference Mitigation

- One of the nation's premier biomedical research organizations – a teaching affiliate of Harvard Medical School – Partners Healthcare, explained 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."

Partners Healthcare System Comments at 3.



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FCC MedRadio Proceeding Body-worn Devices

- In AdvaMed's MedRadio Reply Comments, members of the medical device industry agreed the MICS band should be reserved for implantable medical devices and associated peripherals

1. The core band (i.e., 402-405 MHz) should be reserved for communication between implantable devices and their associated peripherals (e.g., codified in existing MICS rules as "MICS implant programmer/control transmitter"). Our members recognize that implantable medical devices are a special class of devices that require their own spectrum home.

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

- **There is industry consensus**
 - Body-worn devices should not be allowed to operate in the MICS band unless they function as a MICS programmer/controller



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Summary

Medtronic's Position on MITS

- **Background**
 - “Medical Implant Telemetry Service (MITS)” proposed in ETSI ERM TG30 (Wireless Medical Devices)
 - FCC does not recognize this service in Part 95, but has issued temporary waiver allowing such operation
- **Specifications in draft ETSI MICS standard (ETSI EN 301 839-1 V1.2.1 (2007-04)):**
 - Single frequency in the range of 403.5 to 403.8 MHz
 - Implant initiated transmission only (no external device use)
 - The term “Beacon” implies LPLDC transmission by the MICS programmer/controller – yet this type of operation is prohibited
 - Low radiated power (≤ 100 nW); low duty cycle in one hour period ($\leq 0.01\%$)
 - No more than 10 transmissions in a one hour period
- **Medtronic believes this mode of operation is better accommodated in the MEDS bands**



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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



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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

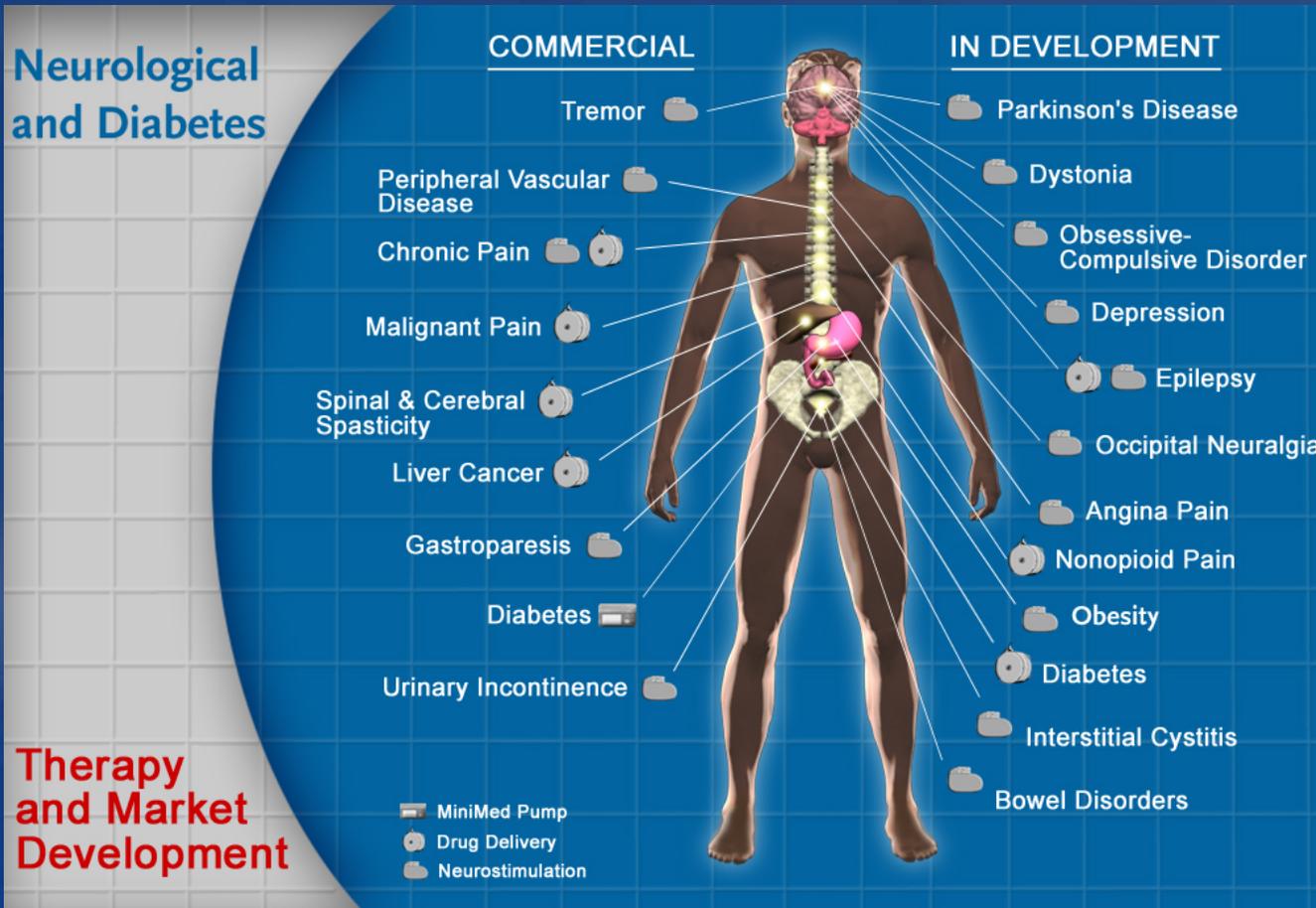
MICS and MEDS are different, but complementary, band allocations



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Summary & Questions



Wireless medical devices will continue to proliferate



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