RFID and Active Implantable Cardiac Rhythm Management Devices Electromagnetic Compatibility

Mitchell J. Shein

Senior Scientific Reviewer

FDA/CDRH

The hats I wear……

- Sr. Reviewer, Division Cardiovascular Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA
- Chair, Association for the Advancement of Medical Instrumentation Cardiac Rhythm Management Devices Committee's Electromagnetic Compatibility Task Force – Authors of AAMI PC69
- Convener, ISO/TC150/SC6-IEC/SC62D JWG Active Implantable Devices – Cardiac Pacemakers and Defibrillators Committee

RF Sensitive Devices

Active Implanted Devices

- Cardiac Pacemakers
- Defibrillators
- Infusion Pumps
- Hearing Aids
- Neurostimulators (Deep brain, spinal cord, etc.)
- Programmable valves/ shunts
- Bladder stimulators
- Gastrointestinal imaging system

RF Sensitive Devices (cont'd)

Non-Implanted Devices

- Non implanted infusion pumps
- Wireless monitors
- Diagnostic Electrocardiographs, Cardiotachometers and Alarms, Arrhythmia Detector and Alarms
- Wheelchairs
- Nitric Oxide Delivery Apparatus
- Surgical Lasers
- Wireless Operating room controllers
- Healthcare Information Systems
- Ventilators

Objective

- Sensing characteristics of implantable pacemakers and ICDs
- Potential implantable pacemakers and ICDs responses to electromagnetic field environments
- EMC standards for pacemakers and ICDs
- Solutions for EMC and limitations of technology

AIMDs for Cardiac applications

- Pacemaker - implantable medical device designed to automatically sense and pace, providing treatment for bradycardia

- ICD - implantable medical device designed to automatically detect and treat episodes of ventricular fibrillation (VF), ventricular tachycardia (VT), faster ventricular tachycardia (FVT), and bradycardia

Potential Pacemaker Response to EMI

- Sensing/ Pacing Inhibition (missed pacing beats)
- Noise reversion to asynchronous pacing
- Tracking, for dual chamber devices
- Rate changes within programmed rate limits, for rate adaptive devices
- Current induced into the lead system, that can trigger an arrhythmia
- Activation of the reed switch (asynchronous pacing)
- Extreme case, but very unlikely: microprocessor reset

Potential ICD Response to EMI

- Oversensing that manifests itself as: inhibition (missed pacing beats), and potential inappropriate delivery of therapy
- Tracking, for dual chamber devices
- Undersensing an arrhythmia
- Current induced into the lead system, that can trigger an arrhythmia
- Reed switch activation (suspends detection)
- Extreme case, but very unlikely: microprocessor reset

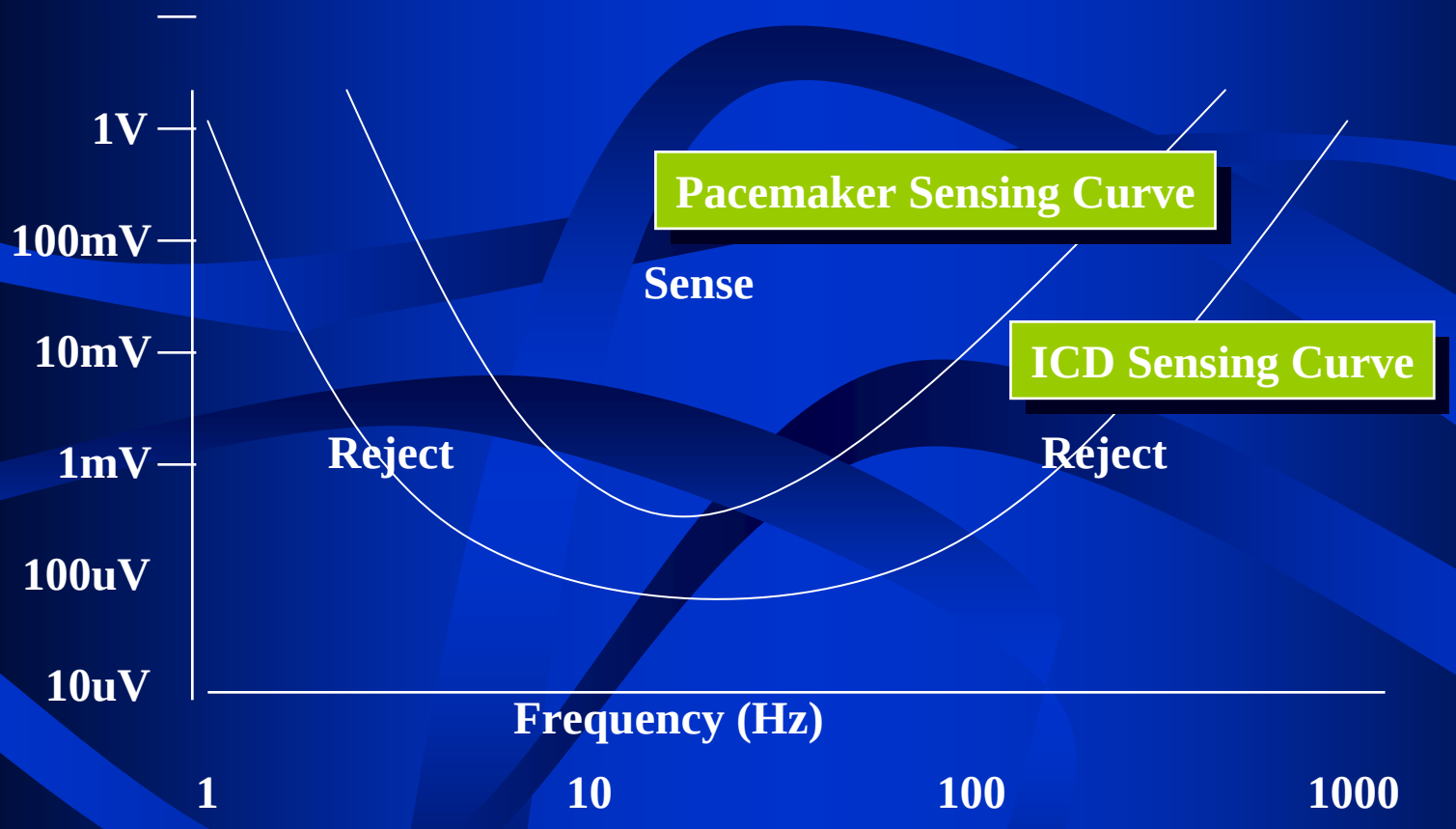
Signal Considerations Related to EMI

- **A typical pulse generator has a sense amplifier "bandpass" from 10 Hz to several hundred Hz**
  - Based on the frequency content of the physiological signal
- **Designed to sense peak values of very low physiological signals**
- **Minimum sensing threshold is dictated by electronic technology and battery capacity limitations:**
  - Sensitivity range: 0.15 - 2.1 mV for ICDs
  - Sensitivity range: 0.18 - 11 mV for pacemakers
  - Most common shipping settings for pacemakers are: 2 mV unipolar and 0.3 mV bipolar

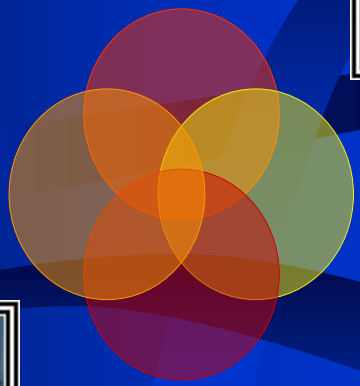
Design Constraints on Pacemaker and ICD Manufacturers

- **The need to sense very low level biological signals**
  - Pacemakers and ICDs are highly sensitive low frequency receivers
- **Small size is highly desirable by patients and physicians for comfort and appearance; however**
  - Limits size and number of components, and
  - Limits the capability to control EMI
- **Low power**
  - Power used to mitigate EMI reduces the life or increases the battery size of the device

Sensing Characteristics



Cardiac Rhythm Management Medical Wireless Focus



- New high frequency (RF) telemetry in the 402-405 MHz range approved for MICS
- Other frequencies in the ISM band being used as well

Product Life Cycle (example)

- Product life/development cycles for pacemakers and ICDs
  - In-house product/therapy development: 2-3 years (may include FCC Regulatory approval for wireless band integration, if applicable)
  - FDA Regulatory approval for new therapy safety efficacy studies: 1.5 – 3 years
  - Device longevity: 5 to 10 years
- TOTAL: 8.5 – 16 years

Potential Sources of EMI (examples from the Emitter Table in ANSI/AAMI Standard PC69, 2000)

- Radio Frequencies Transmitters
- Cellular Telephones/Personal Communication Devices
- Electronic Article Surveillance (EAS) Systems, Metal Detectors
- Power Lines and Equipment that Generate Electric and Magnetic Fields at 60 and 50 Hz

Factors that Impact Medical Device EMC

- EM Source Characteristics:
  - Frequency
  - Modulation
  - Field Strength
- Medical Device/Equipment Susceptibility:
  - Function (bandpass for sensing signals, lead system)
  - Telemetry Function
- Environment
- Customer Education

Challenges to Pacemaker and ICD Manufacturers (examples)

Explosion of new potentially powerful emitters, such as:

- Cell phones and cell phone amplifiers, wireless PDA
- Theft detectors (EAS), metal detectors
- RFID equipment

Cell Phone example

- Cell phone without amplification: 0.3 to 0.6 watts
- Cell phone, 3 watt, after market amplifier and 9 dB gain antenna: 23.8 watts

EMC requirements for pacemakers and ICDs (1)

- Standards with EMC requirements for implantable cardiac devices:
  - Europe: CEN/CENELEC EN 45502-2-1, PrEN 45502-2-2
  - USA: ANSI/AAMI PC69
  - International: ISO 14708-2

EMC requirements for pacemakers and ICDs (2)

- ANSI/AAMI PC69 –
  - dedicated to EMC, and
  - the most comprehensive EMC standard to date for active implantable cardiac devices
- Developed by the AAMI EMC Task Force
- First edition – published in 2000
- Second edition – currently in final ballot

EMC requirements for pacemakers and ICDs (3)

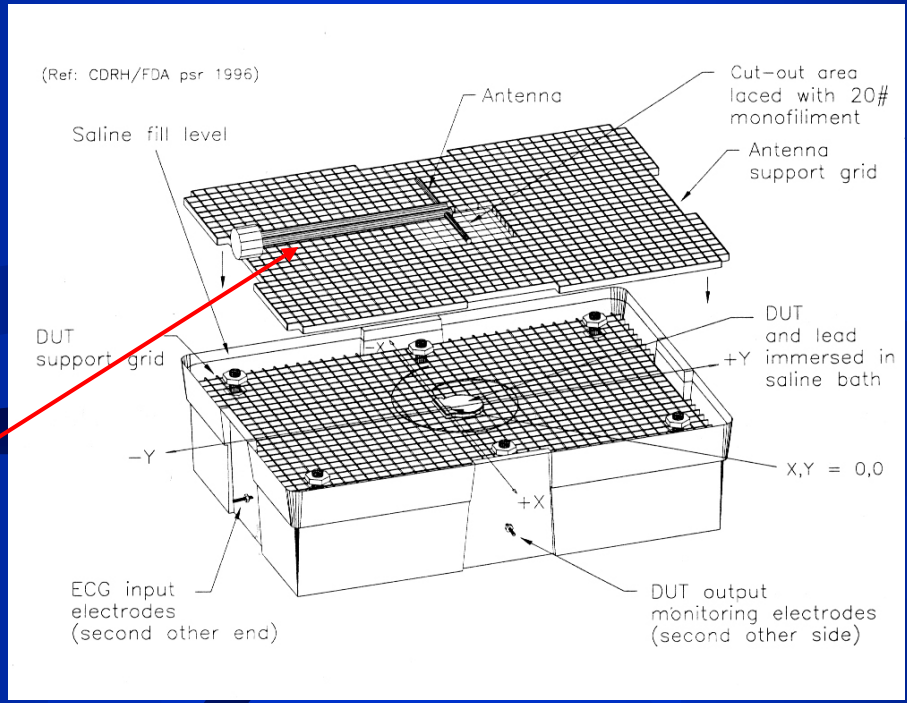
- ANSI/AAMI PC69 – cont.
  - The task force is working on the 3rd edition
  - Testing with RFID equipment was recently conducted at the FDA OSEL EMC Lab
  - RFID equipment included in testing: hand held units at 13.56 MHz and portal at 915 MHz and 132-134 kHz
  - Most RFID manufacturers contacted were willing to work with FDA and the EMC Task Force

EMC requirements for pacemakers and ICDs (4)

- ANSI/AAMI PC69 – cont.
  - Medtronic conducted extensive testing on products currently marketed and legacy product
  - Most RFID systems do not interfere with pacemakers and ICDs
  - However, we noticed that very powerful RFID systems (10 W) at lower frequencies may impact devices in close vicinity
  - We have to understand if the effects have clinical implications

EMC requirements for pacemakers and ICDs (5)

Dipole test



PC69, ANNEX M

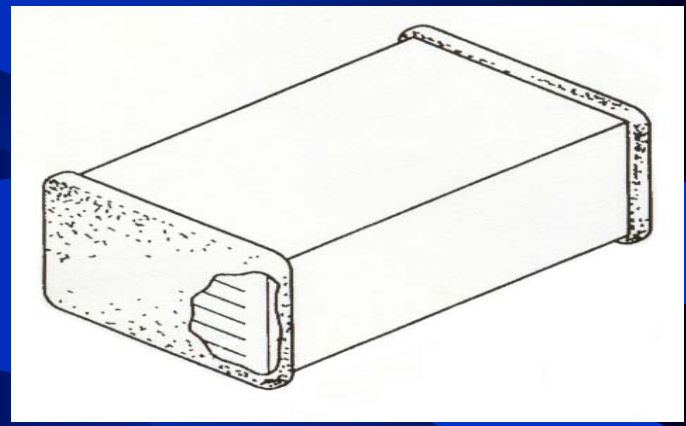
- Provides correlation between levels of test voltages used in the standard and radiated fields strengths, using an implantation lead loop area of 200 cm^2
- Useful tool for emitters interested in field levels for designing systems compatible with pacemakers and ICDs

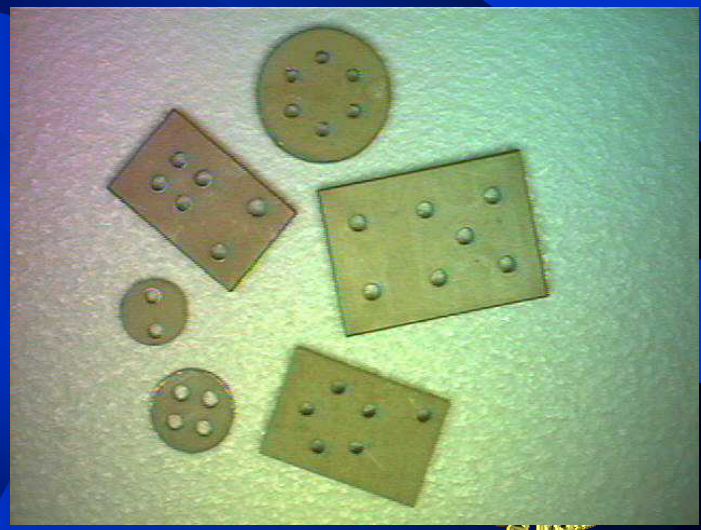
Methods of Mitigating/ Eliminating Susceptibility to EMI (1)

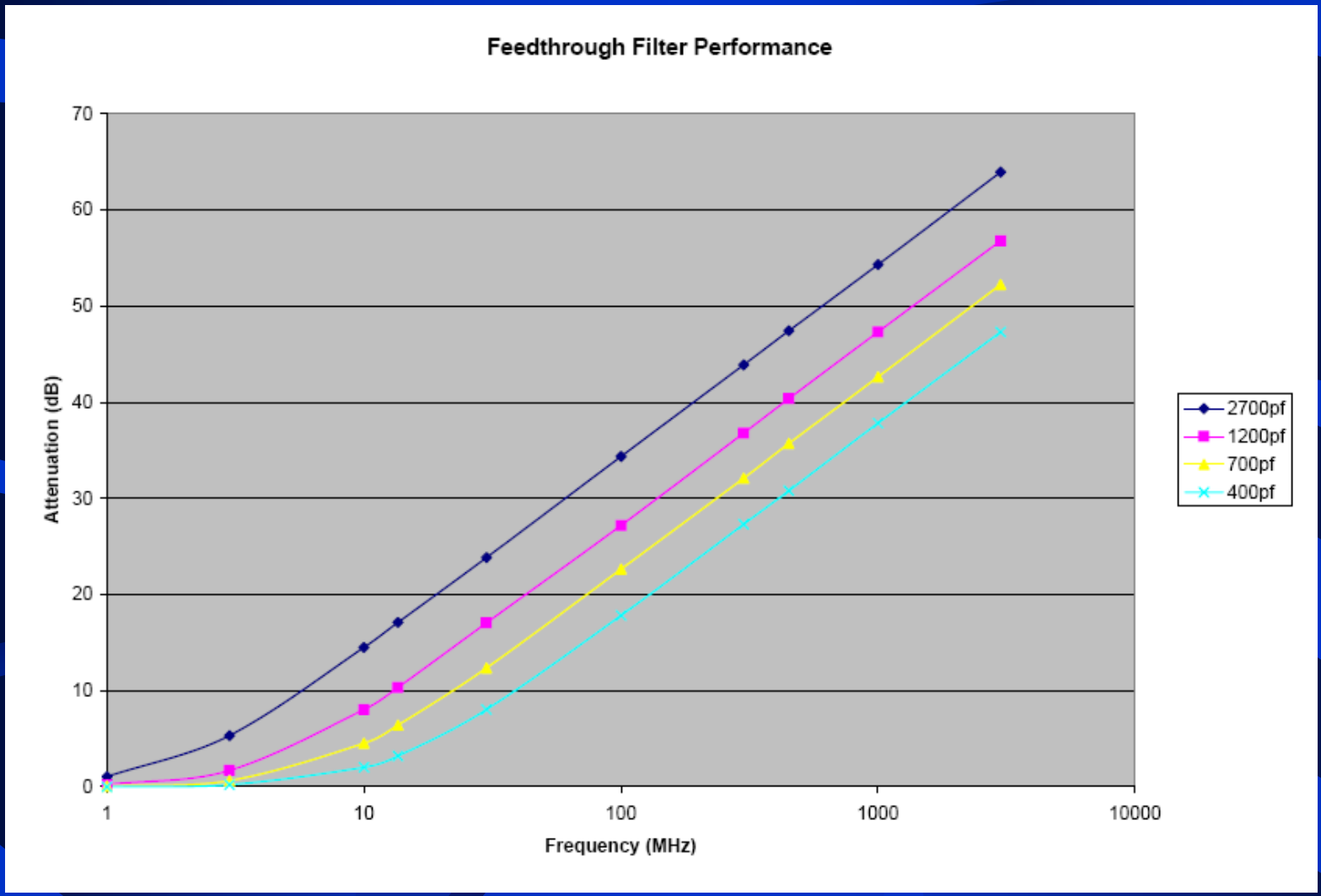
- **Titanium shield housing:**
  - Effective above ~2MHz
  - Effective against electric fields
- **Body tissues:**
  - High frequencies less capable of penetrating deeply into body tissues
  - Leads surrounded by conductive medium are poor high frequency antennas

Methods of Mitigating/ Eliminating Susceptibility to EMI (2)

- **Internal low pass filters:**
  - 2000 to 4700 pf chip capacitors
  - Disadvantages: stray inductance and self resonance
  - Effective from 5 to 100 MHz
- **Integrated feedthrough filters:**
  - 1200 to 9000 pf from each feedthrough lead to housing
  - Mounted immediately inside the housing
  - Effective from 100 MHz to 10 GHz







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Methods of Mitigating/ Eliminating Susceptibility to EMI (3)

- Characteristics of the bandpass
- Reversion circuit - Noise rejection using proprietary methods
- Analog noise filtering through noise monitoring
- Some methods facilitate, in certain conditions, conversion to asynchronous pacing, which has been used as a clinically acceptable alternative to inhibition

Labeling and Customer Education

- Pacemaker/ICD manufacturers are incorporating state of the art technology to make implantable devices less susceptible to EMI
- However, patients and emitter manufacturers should be aware that limitations exist and that there is not complete immunity to EMI
- The industry is working with regulatory bodies and emitter manufacturers to educate patients and physicians and develop appropriate warnings, when required

Labeling and Customer Education - Examples

- Keep cell phones at least 15 cm from the implant
  - Some older pacemaker models do not incorporate feedthrough filters and may be susceptible
- When exiting retail stores through security scanners (EAS gates), Don't Lean and Don't Linger
  - Be aware that EAS systems might be hidden at entrances and exits to many commercial establishments, and avoid these security devices as much as possible
- Show airport security personnel the ID card and ask for alternative search

Emitter Considerations

- **An emitter can be intentional (cell phone), or unintentional (electric shaver)**
- **Factors to consider:**
  - Frequency of the emitter
  - Modulation up to several hundred Hz
  - Peak power
  - Proximity to the patient
  - Duration of exposure
  - Coupling factors

Emitter Regulations

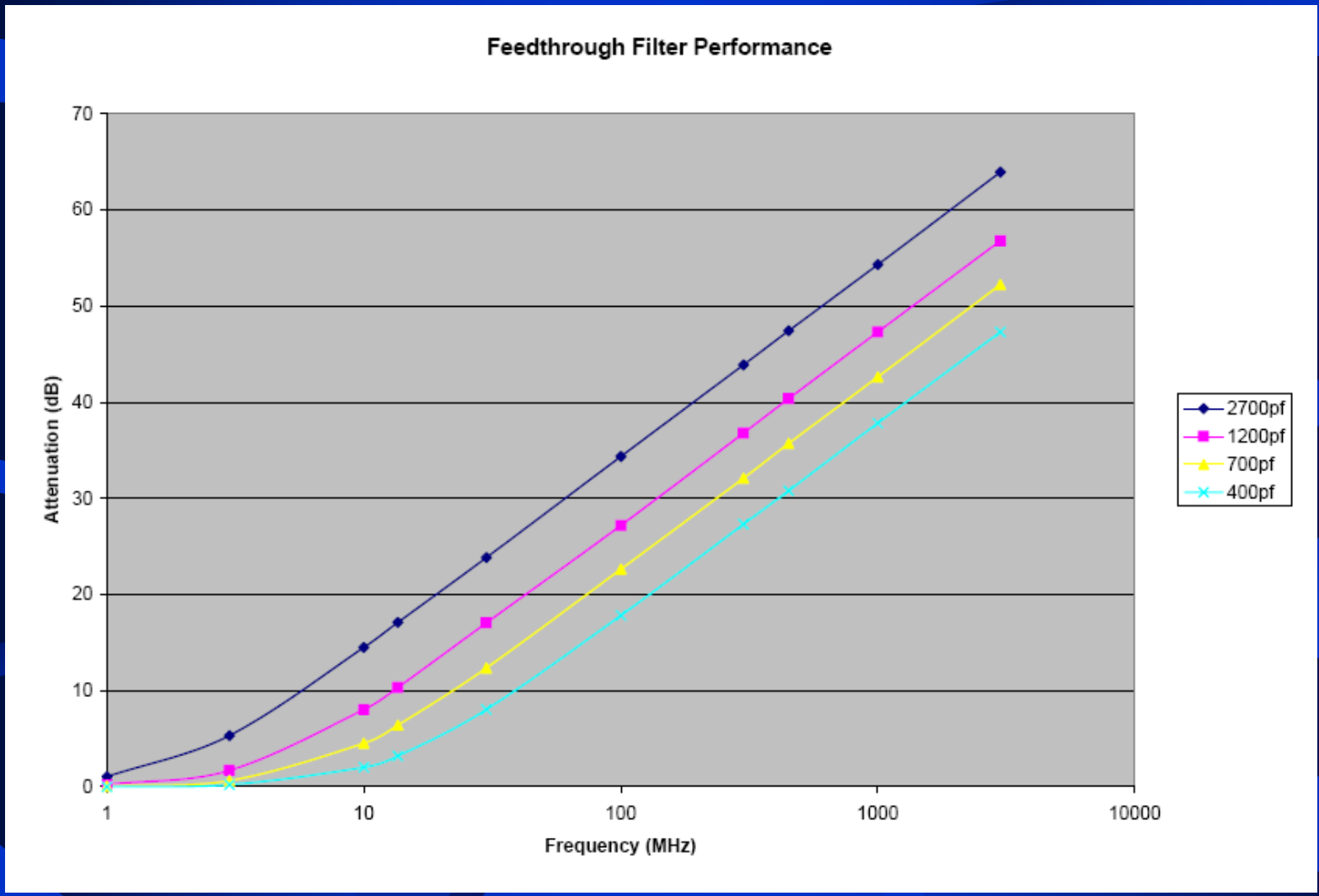
- **Regulatory Agencies (examples):**
  - US – FCC (Federal Communication Commission)
  - Europe – SMA (Spectrum Management Authority)
- **Regulate carrier frequencies**
- **Focus on spectrum use and efficiency**

Standards Governing Transmitter Manufacturers

- Maximum allowable transmitter output power is based on human safety exposure standards (ICNIRP, EC 519/99, IEEE C95.1, IEEE C95.6) based upon:
  - Average power and short-term biological effects (such as tissue heating and nerve stimulation)
- As a result, emitting equipment may produce pulsed signals where peak power greatly exceeds pacemaker/ICD capability of rejecting noise

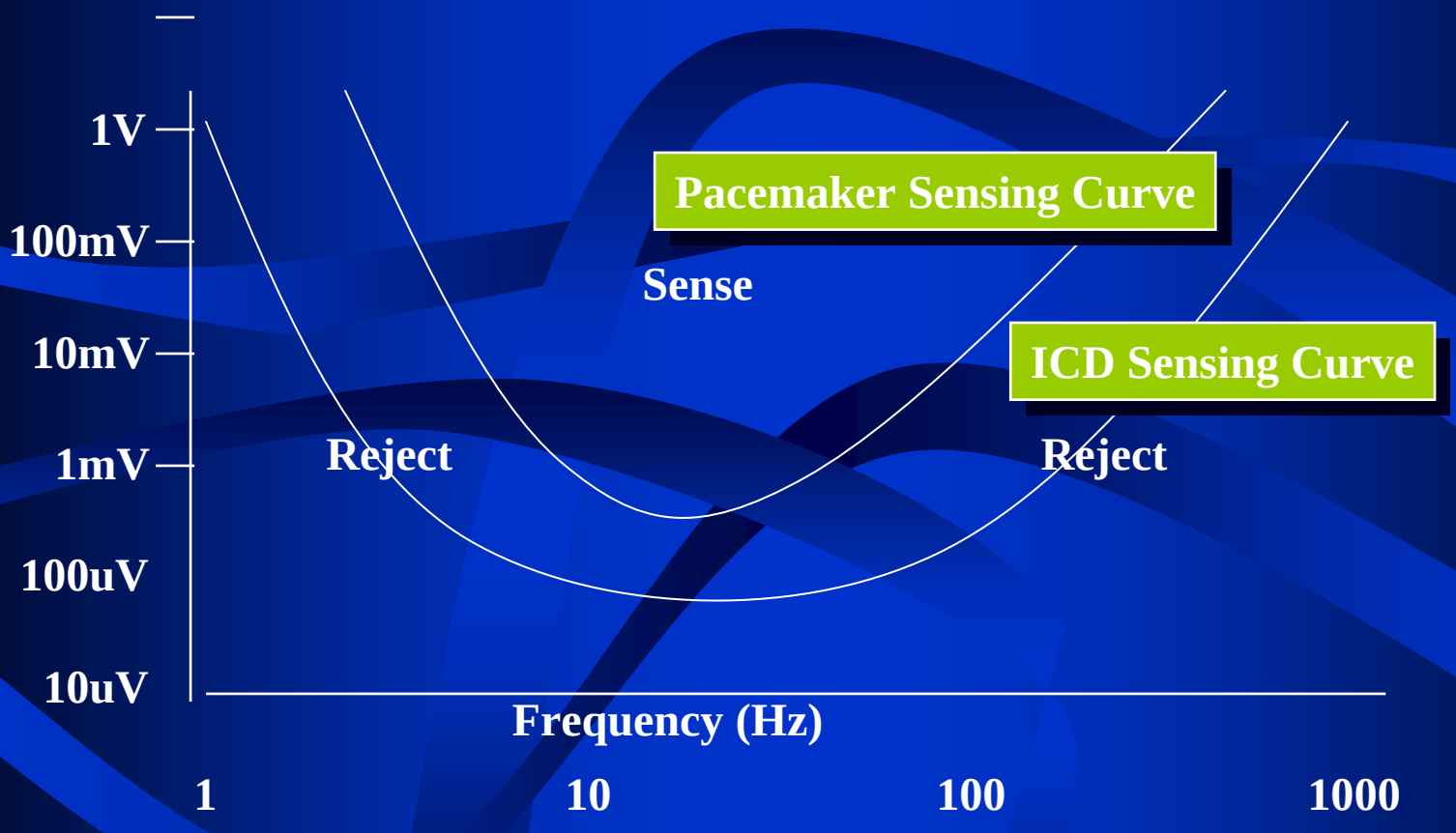
FCC regulations for RFID Frequencies

Band	Frequency	FCC Regulated Field Strength
	134.2 KHz	2400 μV/m at 300 m
ISM	13.56 MHz	15,848 μV/m at 30 m
MICS	433.5-434.5 MHz	55,000 μV/m at 3 m
ISM	902 -918 MHz	50 to 2500 μV/m at 3 m
ISM	2.4 GHz	2500 mV/m at 3 m



Graph courtesy of Greatbatch, Inc.

Sensing Characteristics



Summary (1)

- Control of EMI involves body tissues, shielding, electronic filtering, passive filtering, feedthrough filters, and software features, all working together
- Pacemaker and ICD manufacturers cannot solve all EMI issues: labeling and customer education are required
- New emitters are constantly entering the marketplace, posing new challenging problems

Summary (2)

- Emitters complying with FCC Regulations may still interfere with pacemakers and ICDs
- Emitter manufacturers are encouraged to read the pacemaker and ICD EMC standards and work with the pacemaker/ICD industry to design their devices to avoid pacemaker/ICD bandpass, to the extent possible

THANK YOU!

U.S. Food and Drug Administration
Division of Cardiovascular Devices

MITCHELL J. SHEIN
Electrical Engineer
Pacing Defibrillator & Leads Branch

Office of Device Evaluation (HFZ-450)
9200 Corporate Blvd.
Rockville, MD 20850

(240) 276-4078
Fax (240) 276-4002
mitchell.shein@fda.hhs.gov