Active Implantable Medical Devices and Electromagnetic Compatibility

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What is an arrhythmia

- The heart's natural pacemaker, the sinoatrial node, sends out electrical signals that make the heart beat.
- If the electrical signals come from places other than the heart's natural pacemaker, an abnormal rhythm called an arrhythmia may result.
- If the arrhythmia is a rapid one, usually more than 120 beats per minute, it is called tachyarrhythmia.
- If the arrhythmia is a slow one, usually less than 60 beats per minute, it is called bradyarrhythmia.

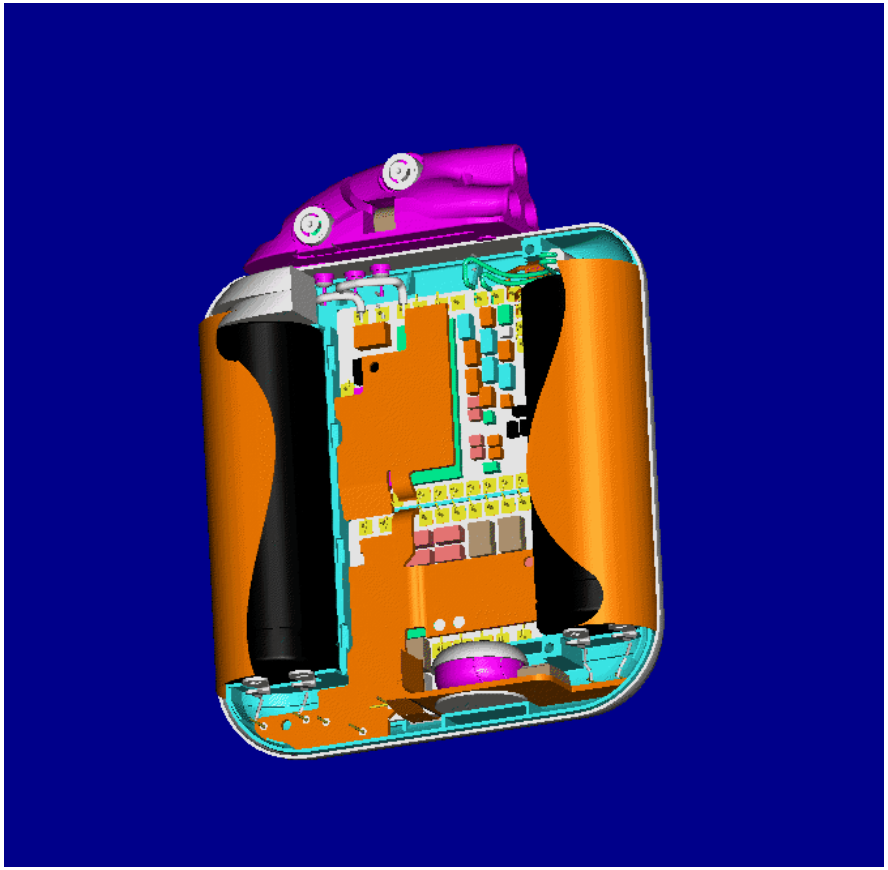
Definitions

- The ICD (Implantable Cardioverter Defibrillator) is an implantable medical device designed to automatically **detect** and **treat** episodes of ventricular fibrillation (VF), ventricular tachycardia (VT), faster ventricular tachycardia (FVT), and bradycardia.
- The Pacemaker is an implantable medical device designed to automatically sense and pace, providing treatment for bradycardia.

Pulse Generator Components

- Hardware: electronic circuitry (for pacing, sensing, therapies delivery), charging circuit (only ICDs), high voltage capacitors (only ICDs), battery cell (s), connector module.
- Firmware

ICD Hardware Components



Sensing and Detection Concepts

- The sense amplifier registers the occurrence of successive cardiac depolarizations, and allows measurement of consecutive time intervals of these events.
- “Sensing” is the noting of a depolarization.
- “Detection” is the processing of these sensed depolarizations and noting the presence of an arrhythmia.

ICD Detection Methods

- Rate - most ICDs rely on an elevated heart rate, for a specified number of beats or time period, as the basic detection criterion.
- Sensing - because the amplitudes of the electrograms associated with VF are so low, ICDs are equipped with highly sensitive amplifiers.

Sense Amplifier Passband and Sensitivity

- A typical pulse generator has a **sense amplifier "passband" from 10 Hz to 100 Hz.**
- Based on the physiological frequency.
- Minimum sensing threshold is dictated by electronic technology and current limitations: 0.15 mV.
- Sensitivity range: 0.15 - 2.1 mV for ICDs.
- Sensitivity range: 0.18 - 11 mV for IPGs.

Sources of EMI

- Power Lines, Equipment that Generate Electric and Magnetic Fields: 60 Hz (North America), 50 Hz (outside North America).
- Radio Frequencies.
- Cellular Telephones/Personal Communication Devices.
- Electronic Article Surveillance (EAS) Systems.
- Magnetic Resonance Imaging (MRI) Systems.
- Various Medical Procedures: Electrocautery, Lithotripsy, Diathermy, External Defibrillation, etc.

EMI Problem Areas

- Modulations: the carrier frequency of the signal might not pose a problem, but **if the modulation is in the 10 -100 Hz** range, it can be demodulated by the pulse generator.
- High-Powered RF Electromagnetic Fields.
- High-Voltage Power Transmission Equipment.

ICD Response to EMI

- Oversensing that manifests itself as: inhibition (missed pacing beats), inappropriate delivery of therapy.
- Tracking for dual chamber devices.
- Undersensing an arrhythmia.
- Microprocessor reset.
- Current induced into the lead system, that can trigger an arrhythmia.
- Activation of the reed switch (suspend detection).

Pacemaker response to EMI

- Sensing/ Pacing Inhibition.
- Noise reversion to asynchronous pacing.
- Tracking for dual chamber devices.
- In rate adaptive devices, the rate changes within programmed rate limits.
- Activation of the reed switch (asynchronous pacing).

EMI Protection

- Titanium Shields - more effective at:
  - » high frequencies
  - » against electric fields
- Body Tissue -
  - » high frequencies less capable of penetrating deeply into body tissue
  - » leads surrounded by conductive medium are poor high frequencies antennas

EMI Protection - Cont.

- Integrated Filtered Feedthroughs - effective at RF frequencies
- Bandpass Filters
  - » passive (centered 25 - 100 Hz)
  - » switched capacitor filters
  - » sensitivity (150 uV to 11 mV @ 40 mSec sine square wave)
- Noise sampling and conversion to asynchronous pacing

Applicable Standards

- EN 50061/prEN 45502-2-1 and -2-2 Requirements:
  - Protection from spurios currents being developed on the lead system which may directly stimulate the heart: 20 Hz to 5 MHz, voltage magnitude 1-6 Vpp CW.
  - Protection from malfunction due to electromagnetic interference - the device shall be constructed so that ambient electromagnetic fileds are unlikely to cause malfunction.

Applicable Standards - Cont.

- Protection against sensing electromagnetic interference - the device shall be constructed so that commonly encountered electromagnetic signals are unlikely to be confused with sensed beats and change the behavior of the device.

- AAMI 1975 Pacemaker Protocol
  - 450 MHz radiated field - minimum 140 V/m RMS.
  - 50, 60, 400 Hz conducted interference.

Applicable Standards - Cont.

- AAMI EMC Protocol - being developed
  - 450 MHz - 3 GHz range - near field dipole antenna test.