

RFID and Pacemakers/ICDs Test Results

Veronica Ivans
CRDM Standards manager

Medtronic

Test Background (1)

- FDA OSEL (Office for Science and Engineering Laboratories) –testing at industry level
 - 18 pacemakers; 19 ICDs
 - Device manufacturers: Medtronic, Boston Scientific, St. Jude Medical, Biotronik, Sorin/ELA Medical
- Seth Seidman – the focal point
- Results presented at RFID Live, Orlando, March 2007

Test Background (2)

- 7 RFID systems:
 - Two 134 kHz
 - Four 13.56 MHz
 - One 915 MHz
 - Hand-held and portal technologies
 - Passive tags

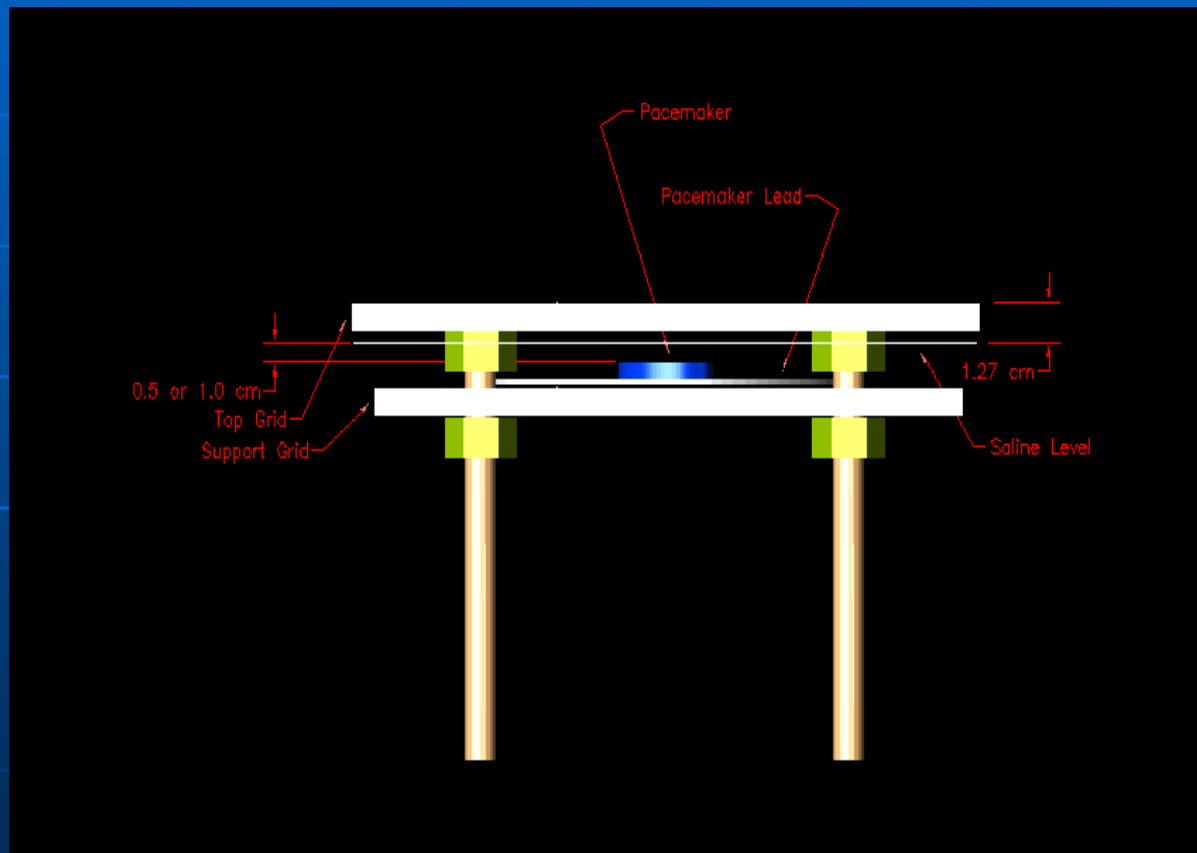
RFID Systems Features (tested at OSEL)

RFID equipment	Carrier frequency MHz	Standard	H-Field @ 2.3 cm (A/m)	Modulation
1	0.134	ISO 11785	65	14.3 Hz with 0.72 duty factor
2	0.134	ISO 11785	60	10.6 Hz with 0.52 duty factor
3	13.56	ISO 15693	4	2.2 Hz with duty 0.99 factor
4	13.56	ISO 15693	6	3.5 Hz with duty 0.921 factor
5	13.56	ISO 15693	2	10.9 Hz with duty 0.11 factor
6	13.56	ISO 15693	7	6.5 Hz with duty 0.92 factor
7	915	ISO 18000-6C	3	56kHz with duty 0.77 factor

Test Setup (1)

- Based on ANSI/AAMI PC69 EMC standard

Test Setup – Side View (2)



Test Protocol

- Developed by the AAMI EMC Task Force
- Steps:
 - Subject implantable device to RFID reader
 - Parameters varied during testing:
 - Separation distance
 - RFID reader orientation
 - Implantable device sensitivity
 - Record all EMI effects

OSEL Test Results (1)

- Pacemaker responses:
 - Pacing inhibition (missed pacing beats)
 - Tracking (due to atrial oversensing the ventricle is paced)
 - Noise reversion mode (pacemaker recognizes interference and paces at fixed rate)

OSEL Test Results (2)

■ ICD

- Pacing inhibition (missed pacing beats)
- Tracking (due to atrial oversensing the ventricle is paced)
- Noise reversion mode (pacemaker recognizes interference and paces at fixed rate) – if the feature is present and programmed
- Inappropriate tachyarrhythmia detection and therapy delivery

OSEL Test Results (3)

- Pacemaker effects:
 - 134 kHz: 83% devices
 - 13.56 MHz: 18%
 - 915 MHz: 6%
- ICD effects:
 - 134 kHz: 71% devices
 - 13.56 MHz: 11%
 - 915 MHz: 0%

OSEL Test Results (4)

- Maximum distance (cm) for any reaction:

Reader	1	2	3	4	5	6	7
Dist (cm)	61	32	20-	4	3	28	10
% tests with effects	78	73	14	5	3	35	3
H-Field (A/m)	65	60	4	6	2	7	3

Medtronic Test Results (1)

- **Medtronic CRDM** conducted additional in-house testing:
 - Same systems as OSEL with additional characterization
 - Added one more RFID reader at 121 kHz with 1.1 Hz modulation; 0.4-1.1 A/m@ 2.3 cm field strength

Medtronic Test Results (2)

- No interaction with RFID system at 915 MHz
- Potential interactions noted with all systems at 121 – 134 kHz
- Potential interactions with one 13.56 MHz system, which is very powerful

General conclusions (1)

- Testing at OSEL and Medtronic showed potential interference
- Most interactions are not clinically significant, but some would require labeling

General conclusions (2)

- 121-134 kHz RFID systems that have high power and modulations in the device bandpass may interfere with pacemakers and ICDs
- 13.56 MHz RFID systems that have high power and modulations in the device bandpass may interfere with pacemakers and ICDs; the likelihood is lower than with the above systems
- 915 MHz RFID systems have very low likelihood to interfere with pacemakers and ICDs

Next Steps (1)

- OSEL and the industry to conduct final evaluation
- Test protocol was updated and it will include additional steps to avoid potential misinterpretation of EMI events
- As some RFID systems allow changing the modulation, additional evaluation will be conducted to potentially identify modulations that produce no interference

Next Steps (2)

- Additional RFID systems to be tested at OSEL with entire device industry participating
- Testing will start in January 2008

Questions?

Veronica.ivans@medtronic.com

Telephone: +1 (763) 526 2367