COE CST 3rd Annual Technical Meeting:

Task 295:Effects of EMI and Ionizing radiation on Implantable Medical Devices

James M. Vanderploeg, MD, MPH

Baylor College of Medicine

utmb Health Aerospace Medicine

NSBRI National Space Biomedical Research Institute

October 30th, 2013

COE CST

Center of Excellence for Commercial Space Transportation

Overview

utmb Health
Aerospace Medicine

- Team Members
- Purpose of Task
- Research Methodology
- Results
- Next Steps
- Contact Information

Team Members

- **PI: James Vanderploeg, MD** (UTMB Aerospace Medicine)
- **Co-I: Tarah Castleberry, DO** (UTMB Aerospace Medicine)
- **Resident: David Reyes, MD** (UTMB Aerospace Medicine)
- **Steven McClure** (NASA Jet Propulsion Laboratory)
- **Jeffery Chancellor** (Center for Space Medicine, Baylor College of Medicine)
- **Nicholas Stoffle** (NASA Johnson Space Center, Space Radiation Analysis Group)
- **Program Manager:** Ken Davidian (FAA)
- **Technical Monitor:** Henry Lampazzi

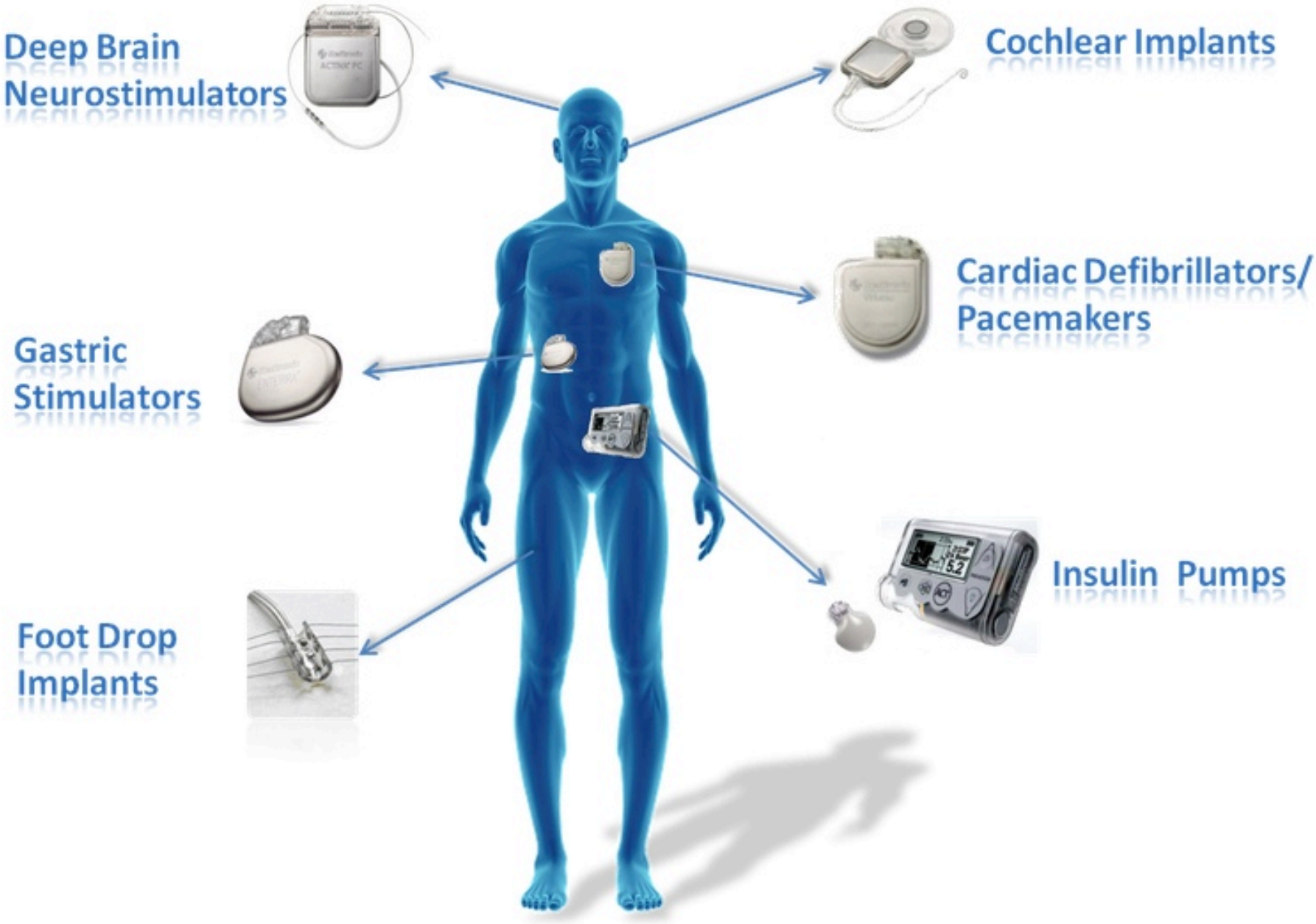
Purpose of Task

utmb Health
Aerospace Medicine

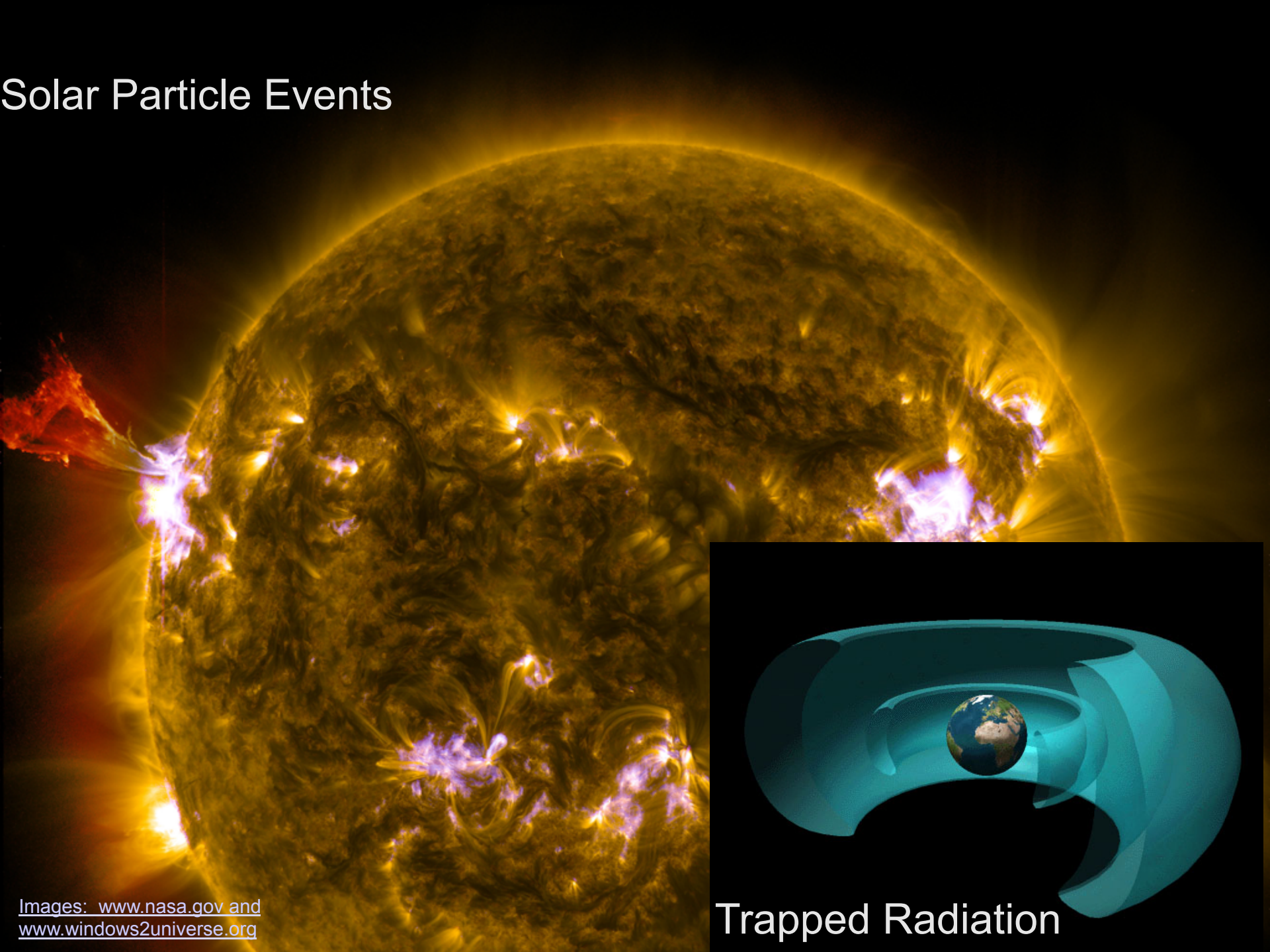
- Investigate known effects of radiation environments on the performance of implanted medical devices (IMDs)
- Extrapolate impacts on function of IMDs in commercial spaceflight participants flying at suborbital and LEO altitudes

Rationale

- Commercial spaceflight participants may have varying degrees of health and potentially significant medical problems
- The effect of solar and galactic radiation on IMDs is unknown, particularly on the internal components, electronics, and function of the device itself

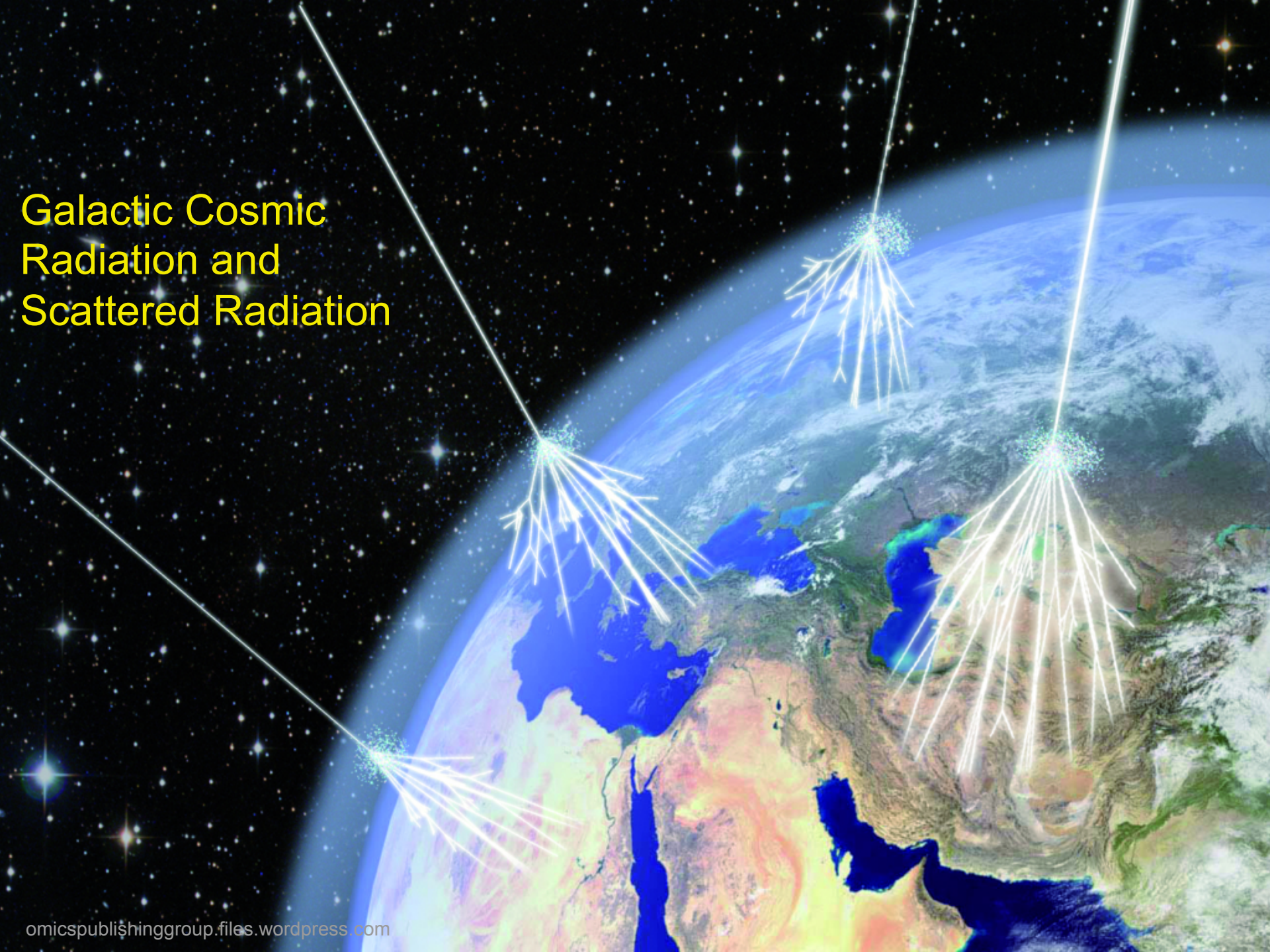

Deep Brain Neurostimulators
Cochlear Implants
Cardiac Defibrillators/ Pacemakers
Gastric Stimulators
Insulin Pumps
Foot Drop Implants

Solar Particle Events



Trapped Radiation

Images: www.nasa.gov and www.windows2universe.org



Research Methodology

- Systematic literature review for human studies involving EMI and effects of diagnostic and therapeutic radiation on IMDs
  - PubMed
  - MedLine
  - Google Scholar

Results

- Effects of EMI on IMDs
  - Transient
  - <6” distance

Nonmedical EMI Sources

Table 1. Possible Sources of Electromagnetic Interference From Nonmedical Sources

Source	Possible Effect(s)
Cell phones	None
Security gates	EMI sensing
EAS systems	EMI sensing
Taser	Rapid pacing (shunting of electrical activity to the lead tip); EMI sensing
Magnets (speakers, headphones, jewelry clasps)	Magnet mode
iPods	Interference with ECG recording systems
Other (microwaves)	None

Abbreviations: EAS, electronic article surveillance; ECG, electrocardiographic; EMI, electromagnetic interference.

Clin. Cardiol. 35, 5, 276–280 (2012)
J. Misiri et al: EMI interactions with ICDs: Part I
Published online in Wiley Online Library (wileyonlinelibrary.com)
DOI:10.1002/clc.21998

Results

- Effects of radiation on IMDs
  - Diagnostic (CT scan) – transient effects, ~10mGy
  - vs. Therapeutic (tumor treatment) – High-energy can cause device malfunction at doses as low as 40mGy
  - vs. Space Environment – Suborbital effect low
  - Transient, Cumulative
  - Single event upset (SEUs) – alter memory, but can effect device function

Single Event Effects

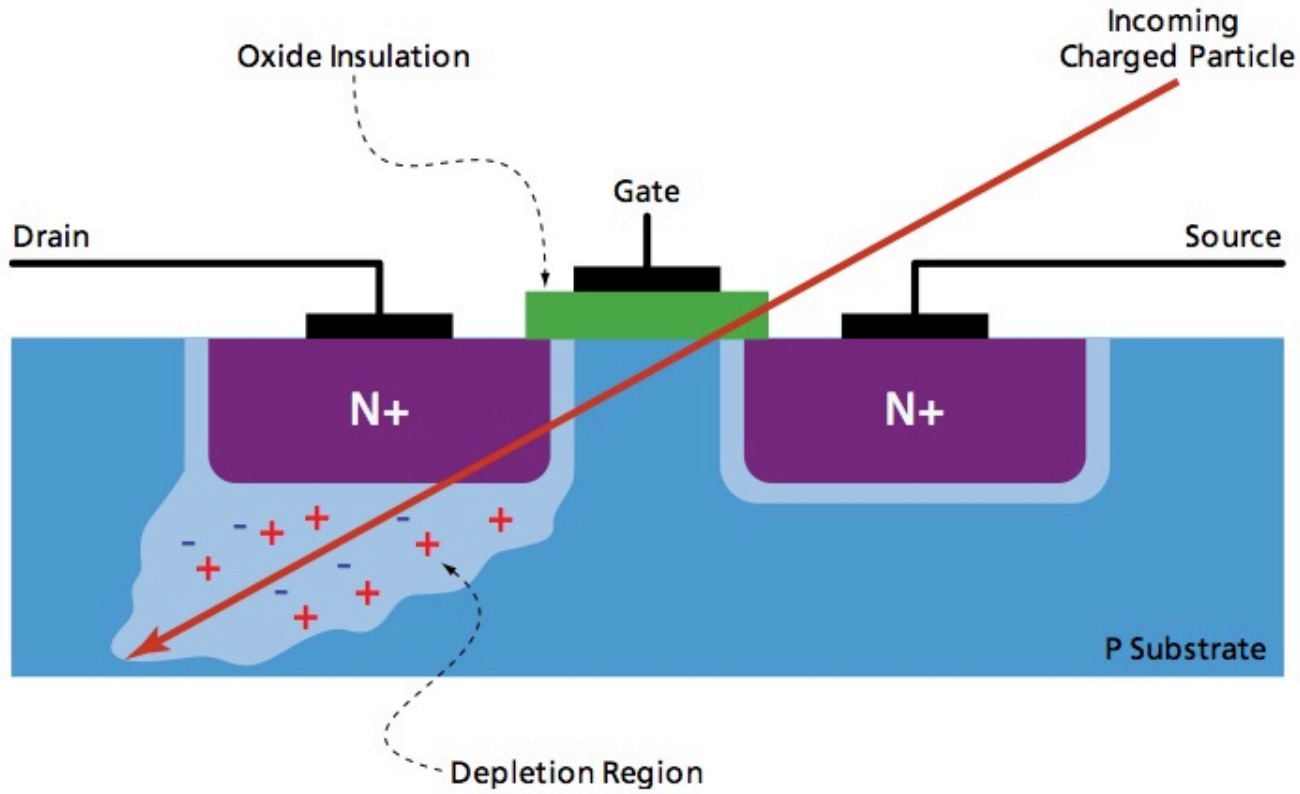
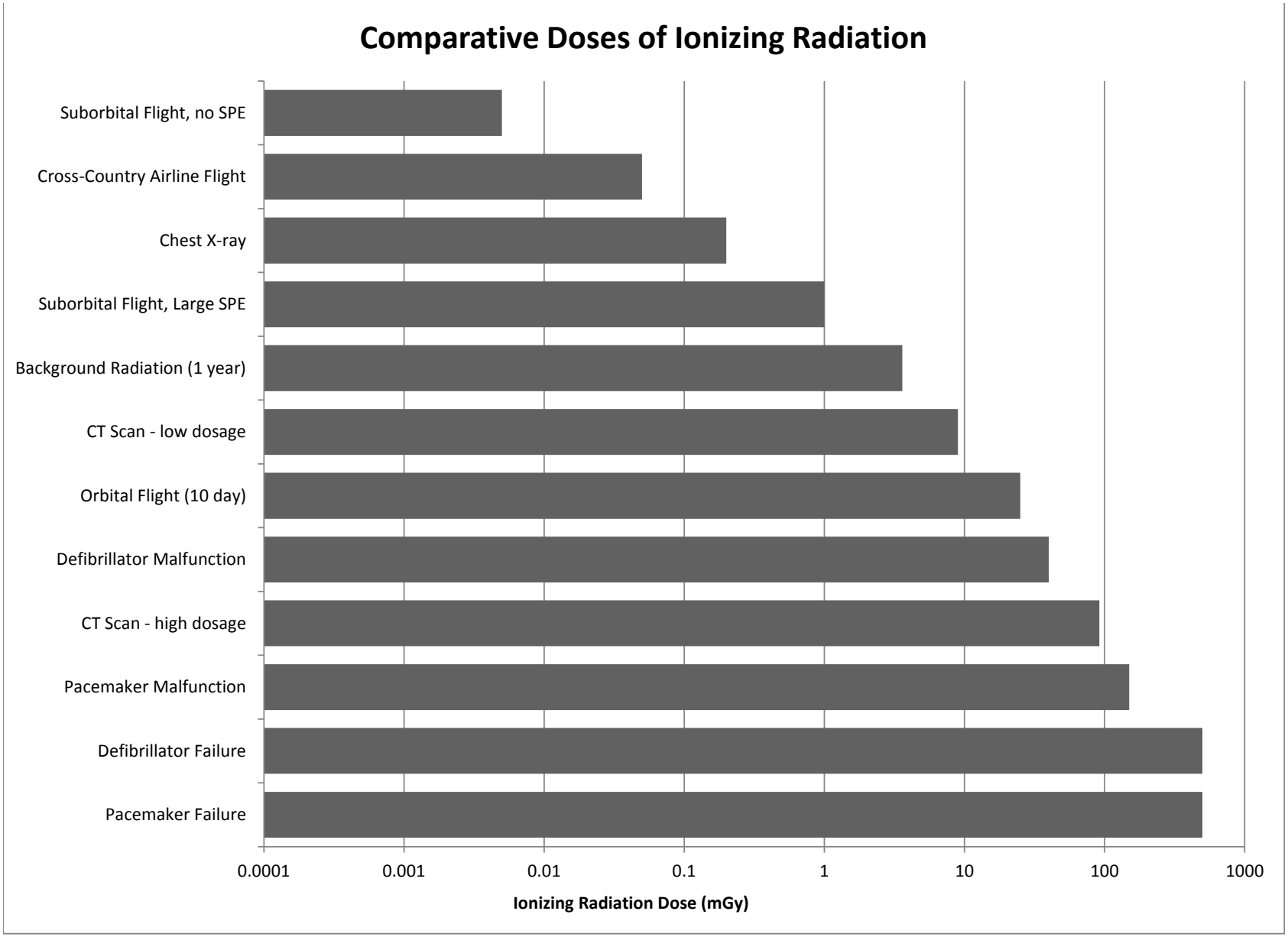


Figure 1: **Charged Particle Causing an SEU**

Microsemi Corp (2010), Single-event upsets (SEUs) and medical devices, Microsemi Corp White Paper, Irvine, CA, December 2010.


Comparative Doses of Ionizing Radiation
Suborbital Flight, no SPE
Cross-Country Airline Flight
Chest X-ray
Suborbital Flight, Large SPE
Background Radiation (1 year)
CT Scan - low dosage
Orbital Flight (10 day)
Defibrillator Malfunction
CT Scan - high dosage
Pacemaker Malfunction
Defibrillator Failure
Pacemaker Failure
0.0001
0.001
0.01
0.1
1
10
100
1000
Ionizing Radiation Dose (mGy)

Results

Mission Type	Radiation Relative to Earth Surface	Possible Dose	IMD Effects
Round Trip, Cross-Country Flight (12 Km)	Radiation Belts – not encountered SPE – slight increase, latitude dependent GCR – minimal additional from ground levels	0.05 mGy	Very low rate of SEU
Suborbital (100 Km)	Radiation Belts – not encountered SPE – slight increase, latitude dependent GCR – minimal additional from ground levels	0.00034 – 0.0026 mGy (no SPE) [1] 0.2 – 1 mGy (large SPE) [1]	Very low rate of SEU due to very short exposure time
Orbital (ISS orbit at ~400 Km)	Radiation Belts – orbit dependent SPE – significant increase GCR – increased	3 – 25 mGy/ 10 days [1] 0.18 to 2.1 mGy per day 1.8 to 21 mGy / 10 days [2] 250 mGy / 100 days [2]	Rate of SEU or other effects dependent on duration of mission. Malfunction likely if > 10 days Eventual failure possible for long-duration flights

Conclusion

- While significant radiation exposure in suborbital flight is unlikely, multi-day orbital exposures could approach levels of radiation exposure associated with potential device malfunction. Individuals with IMDs should experience few, if any, radiation-related device malfunctions during suborbital flight, but could have problems with radiation exposures associated with longer, orbital flight.

Next Steps

utmb Health
Aerospace Medicine

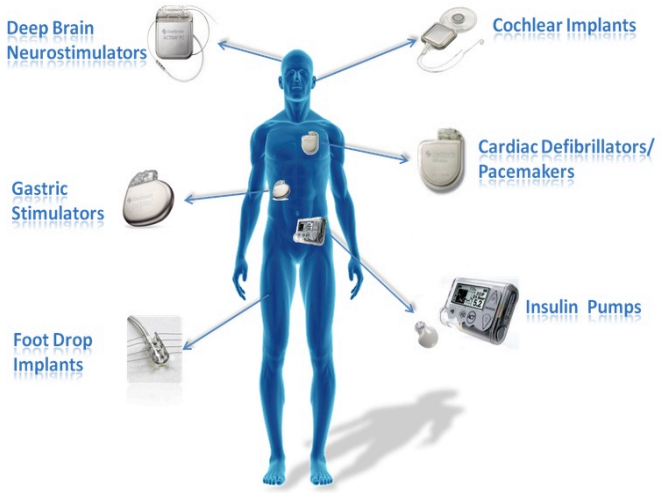
- Manuscript editing
- Publish results

Contact Information

Jim Vanderploeg, MD, MPH (jmvander@utmb.edu)
Tarah Castleberry, DO, MPH (tlcastle@utmb.edu)

2.102 Ewing Hall, UTMB
301 University Blvd.
Galveston, Texas 77555-1110
Phone: 1-409-747-6131
Fax: 1-409-747-6129

Task 295:Effects of EMI and Ionizing radiation on Implantable Medical Devices



Project At-A-Glance

- University: The University of Texas Medical Branch
- Principal Investigator: James Vanderploeg, MD, MPH
- Student Researchers: David Reyes, MD, MPH

Relevance to Commercial Spaceflight Industry

- Commercial spaceflight participants (SFPs) represent a population with potentially significant medical problems, including use of Implantable Medial Devices (IMDs)

Statement of Work

- Investigate known effects of radiation environments on the performance of implanted medical devices (IMDs)
- Extrapolate impacts on function of IMDs in commercial spaceflight participants flying at suborbital and LEO altitudes

Status

- Completed literature review and preliminary manuscript

Future Work

- Review by radiation specialists
- Publish results

utmb Health Aerospace Medicine

Baylor College of Medicine

BACKUP SLIDES

Response of CIED to EMI

Table 2. Possible Clinical Responses to Electromagnetic Interference Depend on Device and Patient Characteristics

Device/Patient	Possible Observed Responses
Device type	
Pacemaker: ventricular channel	Asynchronous pacing due to activation of noise algorithms; safety pacing (pacing at short AV intervals); inhibition of ventricular pacing; magnet mode
Pacemaker: atrial channel	Asynchronous pacing; inhibition of atrial pacing; mode switch; magnet mode
ICD	Inappropriate antitachycardia therapy; magnet mode
Patient characteristics	
Pacemaker-dependent patient	Inhibition of pacing could cause slow heart rates and result in dizziness, syncope, etc.; inappropriate tracking could lead to fast paced rates and rapid heart rates; inappropriate sensing of EMI by an ICD could lead to inappropriate antitachycardia therapy, such as pacing or a shock.
Non–pacemaker-dependent patient	Inhibition of pacing generally does not cause symptoms; inappropriate tracking could lead to fast paced rates and rapid heart rates; asynchronous pacing can cause palpitations and rarely may lead to initiation of arrhythmias; inappropriate sensing of EMI by an ICD could lead to inappropriate antitachycardia therapy, such as pacing or a shock.

Abbreviations: AV, atrioventricular; EMI, electromagnetic interference; ICD, implantable cardioverter-defibrillator.

Clin. Cardiol. 35, 5, 276–280 (2012)
J. Misiri et al: EMI interactions with ICDs: Part I
Published online in Wiley Online Library (wileyonlinelibrary.com)
DOI:10.1002/clc.21998

Medical EMI effects

Table 1. Recommendations to Minimize Electromagnetic Interference in Medical Settings

Electrosurgery
1. Maximize distance between site of monopolar electrosurgery and the CIED. Consider bipolar electrosurgery if required near the CIED. 2. Use the minimum power settings required for adequate electrosurgery. 3. For monopolar electrosurgery, place the return electrode at a site where the current path is kept as far as possible from the CIED. Often, the thigh on the leg contralateral to the CIED will be the best location. 4. For surgeries below the umbilicus, often no specific procedures are required for CIEDs. However, in some cases (patients with ICD or who are pacemaker dependent), reprogramming or magnet application may be considered. 5. Procedures above the umbilicus are more likely to be associated with EMI, and reprogramming or magnet application may be required, particularly if the patient has an ICD or is pacemaker dependent. 6. Using short bursts of electrosurgery may be required if inhibition is observed. 7. Continuously monitor the patient with plethysmography or arterial pressure. 8. After the surgery, address any preoperative programming changes that were made, and consider interrogation for any surgery with a higher likelihood of EMI.
MRI (see Table 2)
LVAD
1. Surgeons implanting the HeartMate II LVAD should be notified and be aware of possible loss of ICD telemetry in some types of ICDs. 2. Interrogate before and immediately after LVAD implantation. 3. If there is loss of ICD telemetry, metal shielding and/or implanting an ICD from a different manufacturer may be required.
Radiation therapy
1. Avoid direct irradiation of the CIED. 2. Consider relocation of the device if it is within the radiation field. 3. Review with the manufacturer the susceptibility of the device to radiation effects. 4. Establish the pacemaker dependency of the patient. 5. Shield the pulse generator if possible. 6. The absorbed dose to be received by the ICD should be estimated before treatment. 7. Continuously monitor the patient's ECG. 8. Consider intermittent testing of the CIED during and after radiation therapy.
Cardioversion
1. Use an anterior-posterior patch position, with the patches positioned as far from the CIED as possible (>8 cm). 2. Evaluate CIED function after cardioversion.
TENS
1. Assess the likelihood and patient risk of TENS for CIED interaction: location of TENS, pacemaker dependency, ICD vs pacemaker. 2. Perform initial supervised testing of TENS use with monitoring to evaluate for interference. 3. Set pacemaker sensing polarity to bipolar. 4. Program OFF impedance-based sensors such as minute ventilation. 5. Place the TENS electrodes close to each other and perpendicular to the device leads. 6. Avoid treatment in the chest area; TENS can often be done safely in the lower extremities.
Radiofrequency ablation, lithotripsy, ECT
1. Generally, no specific programming is required. 2. It is reasonable to have a magnet available. 3. Cardiac monitoring is reasonable, particularly in those patients who are pacemaker dependent.
Abbreviations: CIED, cardiovascular implantable electronic device; ECG, electrocardiogram; ECT, electroconvulsive therapy; EMI, electromagnetic interference; ICD, implantable cardioverter-defibrillator; LVAD, left ventricular assist device; MRI, magnetic resonance imaging; TENS, transcutaneous electrical nerve stimulation.

Guidelines for MRI and CIED

Table 2. Summary of Different Guidelines for the Use of Magnetic Resonance Imaging in Patients With Cardiovascular Implantable Electronic Devices

	AHA Scientific Statement	ESC Position Paper	ACR Guidance Document
Patient selection	Should not be performed in pacemaker-dependent patients or patients with ICDs unless there are "highly compelling circumstances"; discouraged in non–pacemaker-dependent patients unless there is a "strong clinical indication"	Pacemaker-dependent patients (very high risk), ICD patients (high risk), non–pacemaker-dependent patients (low risk)	CIEDs are a relative contraindication to MRI; MRI should be performed on a "case-by-case and site-by-site basis."
MRI considerations	Lowest RF power levels, weakest/ slowest necessary gradient magnetic fields	Field strength <1.5 T; limit SAR — no SAR >2 W/kg; minimize number/ length of sequences; send/receive coils preferred to surface coils	None given
Preoperative CIED evaluation	Interrogate the CIED; program to asynchronous pacing for pacemaker-dependent patients; disable tachycardia therapy in ICD patients	Interrogate the CIED; program to asynchronous pacing for pacemaker-dependent patients; disable tachycardia therapy in ICD patients; program to bipolar sensing; disable special algorithms (eg, rate adaptation)	No specific recommendations
Intraoperative	Monitor heart rhythm and vital signs; audio and visual contact; crash cart available; appropriate personnel available	ECG and pulse oximetry; audio and visual contact; crash cart available; ACLS-certified personnel available; CIED programmer available	ECG and pulse oximetry; crash cart available; radiology and cardiology personnel available
Postoperative CIED evaluation	For any ICDs and pacemaker-dependent patients, interrogate the CIED and reprogram to original parameters; for non–pacemaker-dependent patients, reprogram as needed	Reinterrogate the CIED and reprogram to original parameters if required; interrogate the CIED at 1 week and 3 months	Reinterrogate the CIED; interrogate the CIED again 1–6 weeks after the MRI

Abbreviations: ACLS, advanced cardiac life support; ACR, American College of Radiology; AHA, American Heart Association; CIED, cardiovascular implantable electronic device; ECG, electrocardiography; ESC, European Society of Cardiology; ICD, implantable cardioverter-defibrillator; MRI, magnetic resonance imaging; RF, radiofrequency; SAR: specific absorption rate.

Clin. Cardiol. 35, 6, 321–328 (2012)
J. Misiri et al: EMI interactions with ICDs: Part II
Published online in Wiley Online Library (wileyonlinelibrary.com)
DOI:10.1002/clc.21997