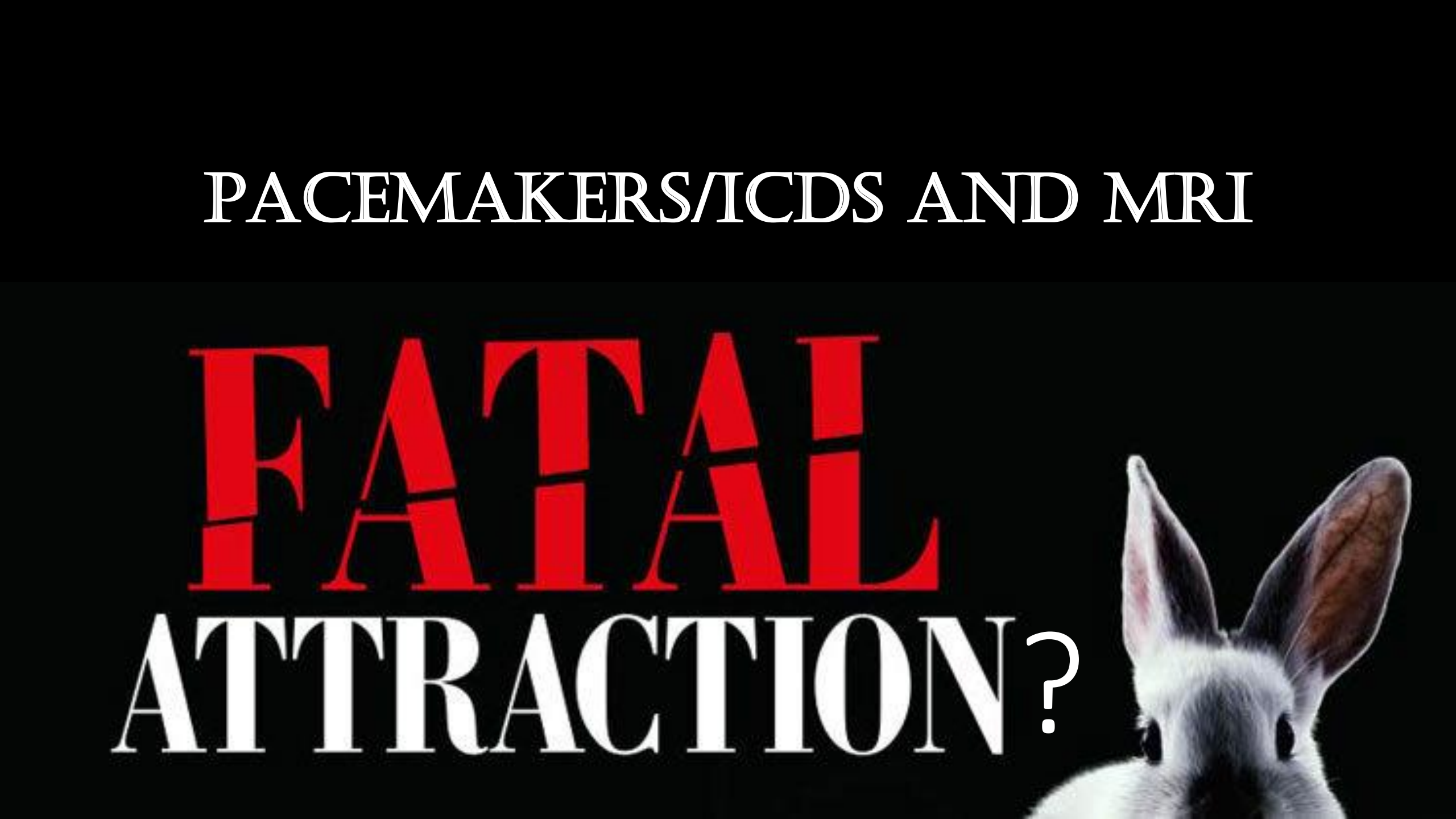
PACEMAKERS/ICDS AND MRI



DANGER
RESTRICTED ACCESS

STRONG MAGNETIC FIELD
The Magnet is Always On!

- **NO CARDIAC PACEMAKERS OR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDs)**

Persons with certain metallic, electronic, magnetic, or mechanical implants, devices, or objects may not enter this area.
Serious injury may result.

Do not enter this area if you have any questions regarding an implant, device, or object. Consult the MRI Technologist or Radiologist.

- **NO LOOSE METAL OBJECTS**

Objects made from ferrous materials must not be taken into this area. Serious injury or property damage may result. Electronic objects such as hearing aids, cell phones, and beepers may also be damaged.

MRI in a Pacemaker Patients is:

1. Absolutely forbidden
2. Now without risk due to MR-conditional devices
3. Requires highly-specialized equipment only available at certain institutions
4. Requires thoughtful programming even in MRI-conditional devices

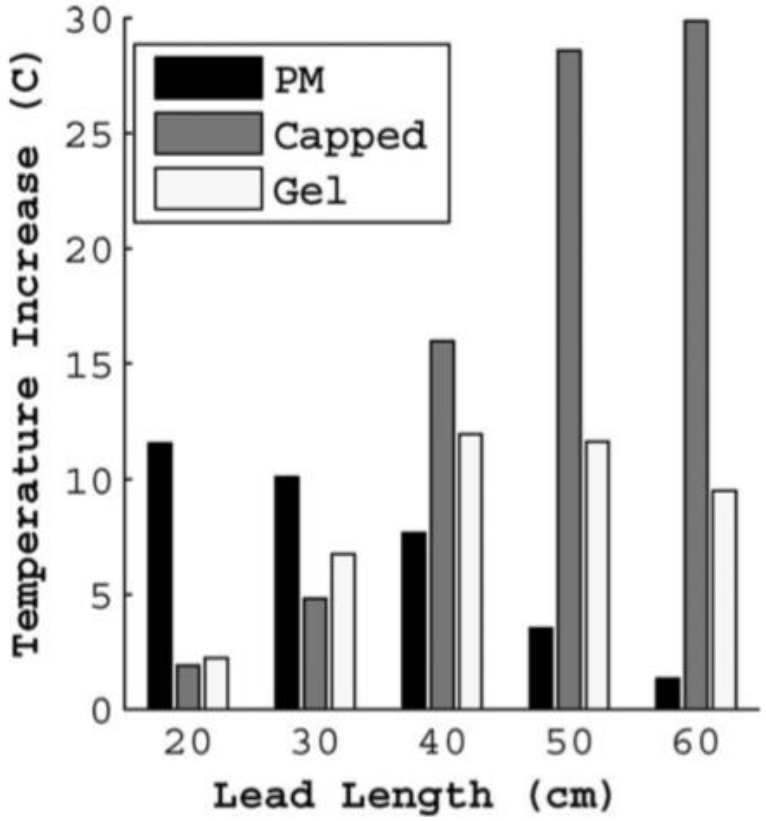
MRI in CIED (Cardiac Implantable Electronic Devices)

- Potential Issues
- Non-MRI Conditional
  - Single Center Studies
  - MagnaSafe Registry
- Abandoned Leads/Mis-Matched Systems
- MRI-Conditional
- Achilles' Heels

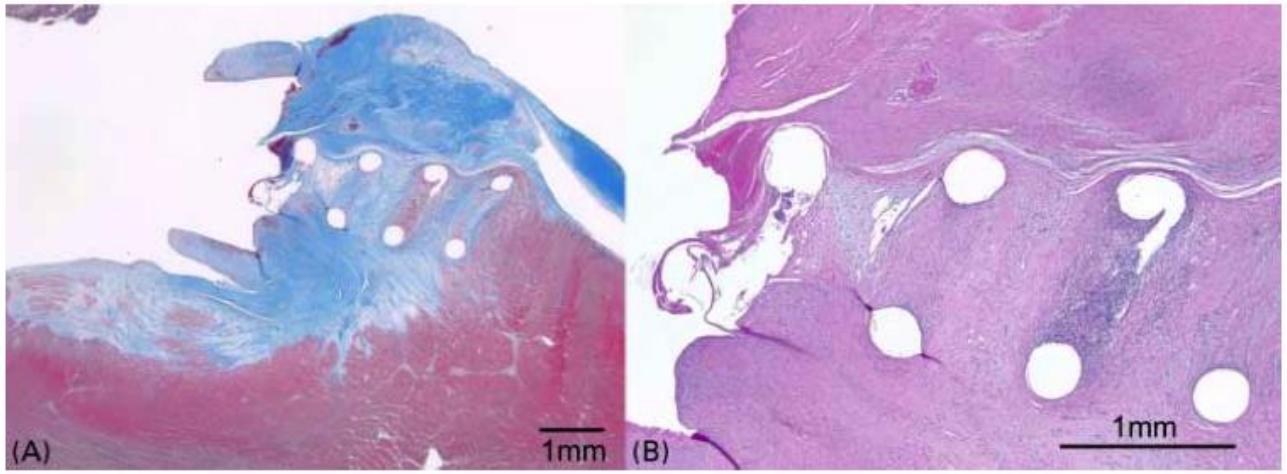
Why Might MR Pose a Problem?

Field	Leads	Generator
Static Magnetic Field Strength 0.5-1.5 Tesla		Device displacement Reed-switch interactions Saturation of transformer core material (ICDs)
Radiofrequency Field Frequency: 21-64 MHz	Heating of lead tip and tissue	Device reprogramming Device reset Rapid pacing
Magnetic Gradient Field Strength: up to 50 mTesla	Induced voltage	Inappropriate sensing Inappropriate triggering

Lead Heating



Biomarker and Histologic Changes



Mollerus M et al *PACE* 2008;31:1241
Bassen HI and Mendoza GG *BioMedical Engineering OnLine* 2009, 8:39
Luenchinger R et al *Eur Heart J* 2005;26:376

Langman DA et al
J. Magn. Reson. Imaging 2011;33:426–431

Single Center Studies of MRI at 1.5 Tesla

Publication	Design	No. of patients	Main findings
Martin *et al.* 2004 [17]	Single-centre prospective	54	Cardiac, vascular, and general 1.5-T MRI studies were performed. Significant changes in 9.4% of leads but change in programmed output required in 1.9%.
Del Ojo *et al.* 2005 [18]	Single-centre prospective	13	No abnormalities associated with 2.0-T MRI.
Nazarian *et al.* 2006 [19]	Single-centre prospective	31	No abnormalities during 1.5-T MRI or 99 days' follow-up.
Sommer 2006 [20]	Single-centre prospective	82	Increased capture threshold post MRI at 1.5 T. Troponin increases observed in four out of 114 examinations.
Mollerus *et al.* 2008 [21]	Single-centre prospective	32	No abnormalities in troponin-I levels or PCTs during and 12 h after 1.5-T MRI.
Naehle *et al.* 2008 [22]	Single-centre prospective	44	No incidents from 55 brain scans using a transmit-receive head coil and an actively shielded 3-T MRI system.
Naehle *et al.* 2009 [23]	Single-centre prospective	18	No significant changes of PCT, lead impedance, and serum troponin I were observed. Battery voltage decreased significantly from pre- to post-MRI
Mollerus *et al.* 2009 [24]	Single-centre prospective	46	A small number of instances of increased ectopy during scans were observed.
Mollerus *et al.* 2010 [13]	Single-centre prospective	103	MRI at 1.5 T was associated with decreased sensing amplitudes and pace impedances up to a peak SAR of 3.2 W/kg.
Buendía *et al.* 2010 [25]	Single-centre prospective	28	Temporary communication failure in two cases, sensing errors during imaging in one case, and a safety signal generated in one pacemaker.
Burke *et al.* 2010 [26]	Single-centre prospective	24	No abnormalities associated with 1.5-T MRI.
Boilson *et al.* 2012 [28]	Single-centre prospective	32	'Power on' resetting of the device noted in five patients. Magnet-mode asynchronous pacing observed during four episodes in three patients.
Cohen *et al.* 2012 [29]	Single-centre retrospective	69	≥0.04 V decreases in battery voltage in 4%; pacing threshold increases ≥0.5 V in 3%; pacing lead impedance changes of ≥50 Ω in 6%. Minor, not clinically important differences in pacing lead impedance and left ventricular pacing threshold.
Muehling *et al.* 2014 [30]	Single-centre prospective	356	No abnormalities were observed during cranial 1.5-T MRI or during follow-up to 12 months. Power-on reset occurred and some reprogramming was necessary in 37 devices (10.4%)

Oklahoma Heart Institute

409 scans (311 patients)
No patient with threshold ≥ 1V
7 ERI/EOL/POR (1.9%)

2019: >1500 MRIs

Adapted From: Jung W et al Curr Opin Cardiol 2015, 30:65–73

Sandler DA et al HRS 2010

MagnaSafe Registry

- Clinically indicated MRIs
  - 1000 Pacemakers
  - 500 ICDs
- Programmed DOO/VOO or ODO/OVO
- Limitations
  - Non-Thoracic
  - 1.5 Tesla
  - No abandoned leads
  - No ERI devices

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator

Robert J. Russo, M.D., Ph.D., Heather S. Costa, Ph.D., Patricia D. Silva, M.S., Jeffrey L. Anderson, M.D., Aysha Arshad, M.D., Robert W.W. Biederman, M.D., Noel G. Boyle, M.D., Ph.D., Jennifer V. Frabizzio, M.D., Ulrika Birgersdotter-Green, M.D., Steven L. Higgins, M.D., Rachel Lampert, M.D., Christian E. Machado, M.D., Edward T. Martin, M.D., Andrew L. Rivard, M.D., Jason C. Rubenstein, M.D., Raymond H.M. Schaerf, M.D., Jennifer D. Schwartz, M.D., Dipan J. Shah, M.D., Gery F. Tomassoni, M.D., Gail T. Tominaga, M.D., Allison E. Tonkin, M.D., Seth Uretsky, M.D., and Steven D. Wolff, M.D., Ph.D.

ABSTRACT

BACKGROUND

The presence of a cardiovascular implantable electronic device has long been a contraindication for the performance of magnetic resonance imaging (MRI). We established a prospective registry to determine the risks associated with MRI at a magnetic field strength of 1.5 tesla for patients who had a pacemaker or implantable cardioverter–defibrillator (ICD) that was "non–MRI-conditional" (i.e., not approved by the Food and Drug Administration for MRI scanning).

METHODS

Patients in the registry were referred for clinically indicated nonthoracic MRI at a field strength of 1.5 tesla. Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning. The primary end points were death, generator or lead failure, induced arrhythmia, loss of capture, or electrical reset during the scanning. The secondary end points were changes in device settings.

RESULTS

MRI was performed in 1000 cases in which patients had a pacemaker and in 500 cases in which patients had an ICD. No deaths, lead failures, losses of capture, or ventricular arrhythmias occurred during MRI. One ICD generator could not be interrogated after MRI and required immediate replacement; the device had not been appropriately programmed per protocol before the MRI. We observed six cases of self-terminating atrial fibrillation or flutter and six cases of partial electrical reset. Changes in lead impedance, pacing threshold, battery voltage, and P-wave and R-wave amplitude exceeded prespecified thresholds in a small number of cases. Repeat MRI was not associated with an increase in adverse events.

CONCLUSIONS

In this study, device or lead failure did not occur in any patient with a non–MRI-conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla, was appropriately screened, and had the device reprogrammed in accordance with the prespecified protocol. (Funded by St. Jude Medical and others; MagnaSafe ClinicalTrials.gov number, NCT00907361.)

From the Scripps Research Institute (R.J.R.), the La Jolla Cardiovascular Research Institute (R.J.R., P.D.S.), University of California, San Diego (U.B.-G.), and Scripps Memorial Hospital (S.L.H., G.T.T.), La Jolla, the University of California, Los Angeles, Los Angeles (N.G.B.), and Providence St. Joseph Medical Center, Burbank (R.H.M.S.) — all in California; the Department of Entomology, University of Arizona, Tucson (H.S.C.); Intermountain Medical Center, Salt Lake City (J.L.A., A.E.T.); Inova Heart and Vascular Institute, Falls Church, VA (A.A.); Allegheny General Hospital, Pittsburgh (R.W.W.B.), and Abington Memorial Hospital, Abington (J.V.F.) — both in Pennsylvania; Yale University School of Medicine, New Haven, CT (R.L.); Providence Heart Institute, Southfield, MI (C.E.M.); Oklahoma Heart Institute, Tulsa (E.T.M.); University of Mississippi Medical Center, Jackson (A.L.R.); Medical College of Wisconsin, Milwaukee (J.C.R.); Bassett Medical Center, Cooperstown (J.D.S.), and Advanced Cardiovascular Imaging, Carnegie Hill Radiology, New York (S.U., S.D.W.) — both in New York; Methodist DeBakey Heart and Vascular Center, Houston (D.J.S.); and Baptist Health, Lexington, KY (G.F.T.). Address reprint requests to Dr. Russo at the Department of Molecular and Experimental Medicine, Scripps Research Institute, 10550 N. Torrey Pines Rd., La Jolla, CA 92037, or at russo@scripps.edu.

N Engl J Med 2017;376:755-64.
DOI: 10.1056/NEJMoa1603265

End-Point Event	Pacemaker		ICD	
	Events/Cases	% (95% CI)	Events/Cases	% (95% CI)
Death during the MRI examination	0/1000	0 (0–0.4)	0/500	0 (0–0.8)
Generator failure requiring immediate replacement	0/1000	0 (0–0.4)	1/500*	0.2 (0.04–1.1)
Lead failure requiring immediate replacement†	0/1926	0 (0–0.2)	0/997	0 (0–0.4)
Loss of capture during the MRI examination‡	0/280	0 (0–1.4)	NA	NA
Observed atrial arrhythmia	5/1000	0.5 (0.2–1.2)	1/500	0.2 (0.04–1.1)
Observed ventricular arrhythmia	0/1000	0 (0–0.4)	0/500	0 (0–0.8)
Electrical reset§	6/1000	0.6 (0.3–1.3)	0/500	0 (0–0.8)

* One patient required immediate replacement of an ICD generator when antitachycardia therapy was inappropriately left in the active mode during the MRI examination (with bradycardia therapy disabled). However, no ICD shocks were delivered. On explantation and subsequent off-site examination by the manufacturer, the device was found to be fully functional.
† Data for this event are presented as numbers and percentages of leads rather than cases.
‡ Data are for cases in which the patient had a pacemaker, was found to be pacing-dependent on initial device interrogation, and was paced in an asynchronous mode during the MRI examination. Patients who had an ICD and were found to be pacing-dependent on initial interrogation were excluded from study entry.
§ In six cases, a partial electrical reset of the device occurred. There were no cases in which full electrical reset of the device occurred.

MagnaSafe Registry
N Engl J Med 2017;376:755-64

CMS.gov
Centers for Medicare & Medicaid Services

Decision Memo 4/10/2018

- MRI field strength is 1.5 Tesla
- The device has no fractured, epicardial, or abandoned leads
- The facility has implemented a checklist which includes the following:
  - Patient assessment is performed to identify the presence of the device
  - Risks and benefits of the MRI scan are communicated with the patient
  - The device is interrogated and programmed appropriately during the scan
  - A qualified physician, nurse practitioner or physician assistant with expertise with CIEDs must directly supervise as defined in 42 CFR § §410.28 and 410.32
  - Patients are observed throughout the MRI scan via visual and voice contact and monitored with equipment to assess vital signs and cardiac rhythm
  - **An advanced cardiac life support provider must be present for the duration of the scan;**
  - A discharge plan that includes before being discharged from the hospital/facility, the patient is evaluated and the device is re-interrogated immediately after the MRI scan to detect and correct any abnormalities that might have developed during the MRI

Abandoned Leads

Mayo: Higgins JV et al *PACE* 2014;37:1284-1290

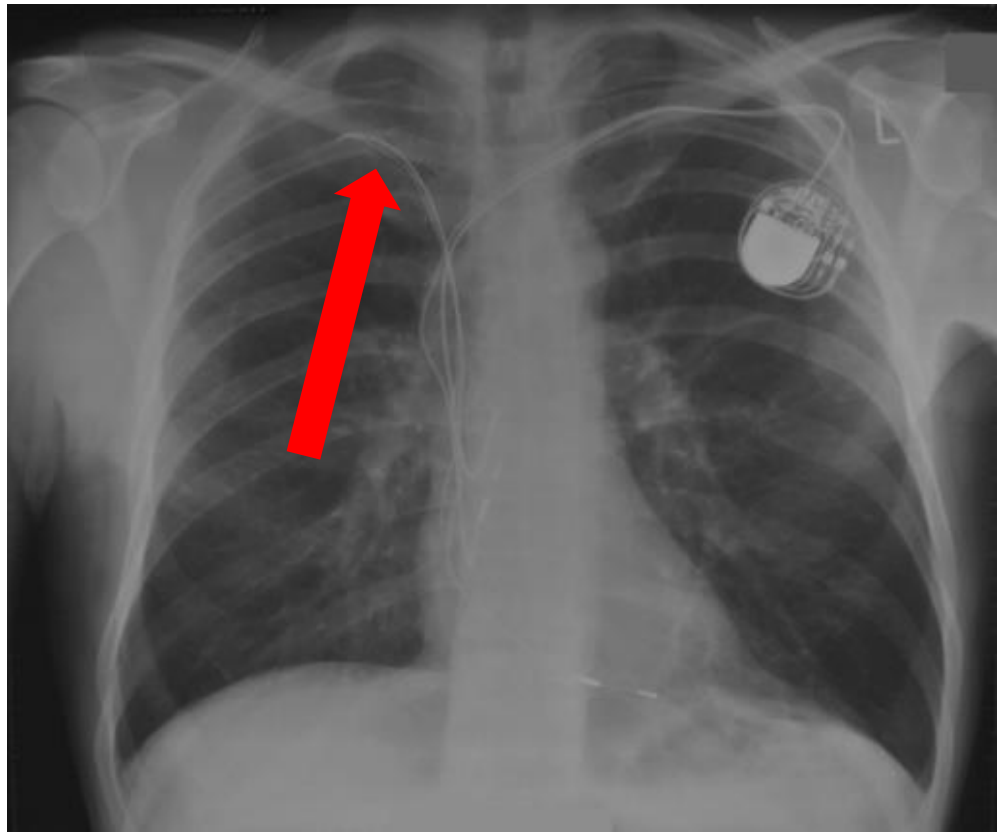
- 19 patients
  - 35 scans, mean 1.63 abandoned leads
- No adverse events

Mayo: Padmanabhan D et al HRS 2017

- 57 patients
  - 70 scans and 63 abandoned leads
- No adverse Events

U of Penn: Brunker T et al: HRS 2017

- 24 patients
  - 34 scans, mean 1.45 abandoned leads
- No adverse events



Thoracic MRI

University of Arizona: Nyotowidjojo IS et al *PACE* 2018;41:589-96

- 238 patients (339 scans)
- No difference in performance thoracic vs non-thoracic

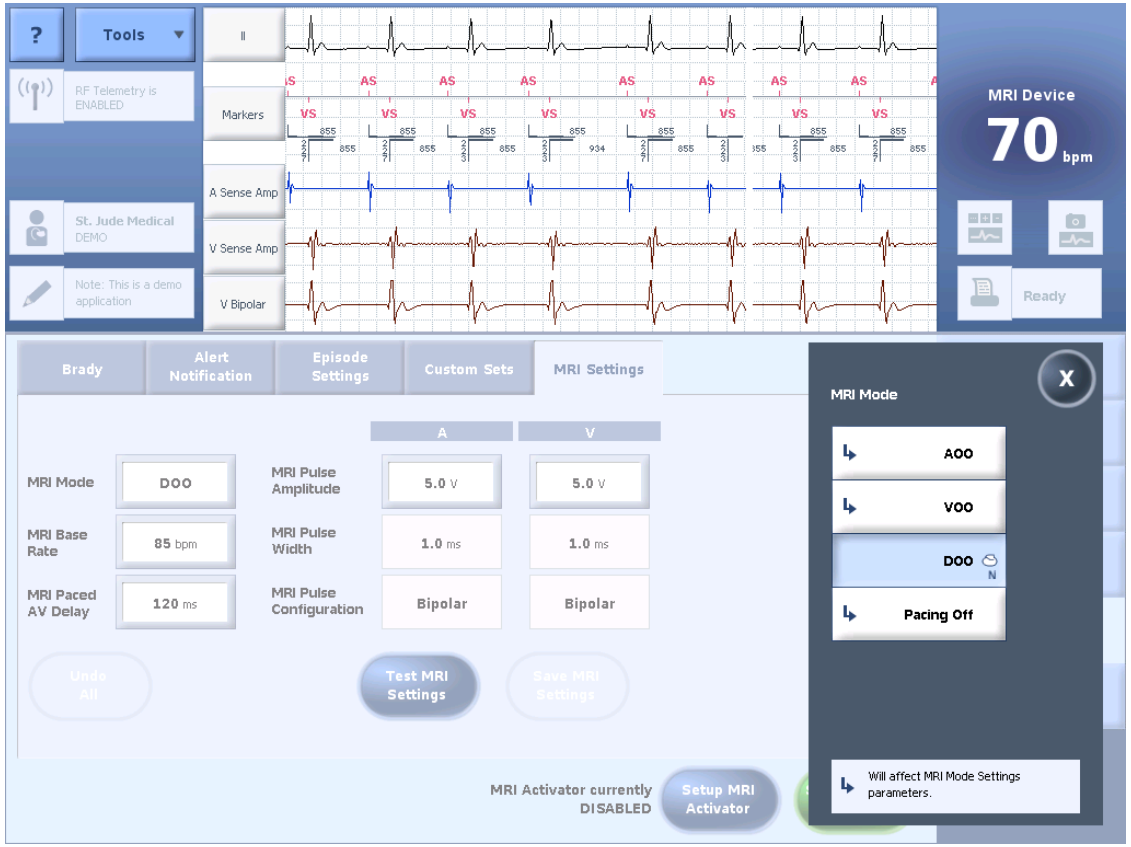
Mismatched CIED Generator and Leads

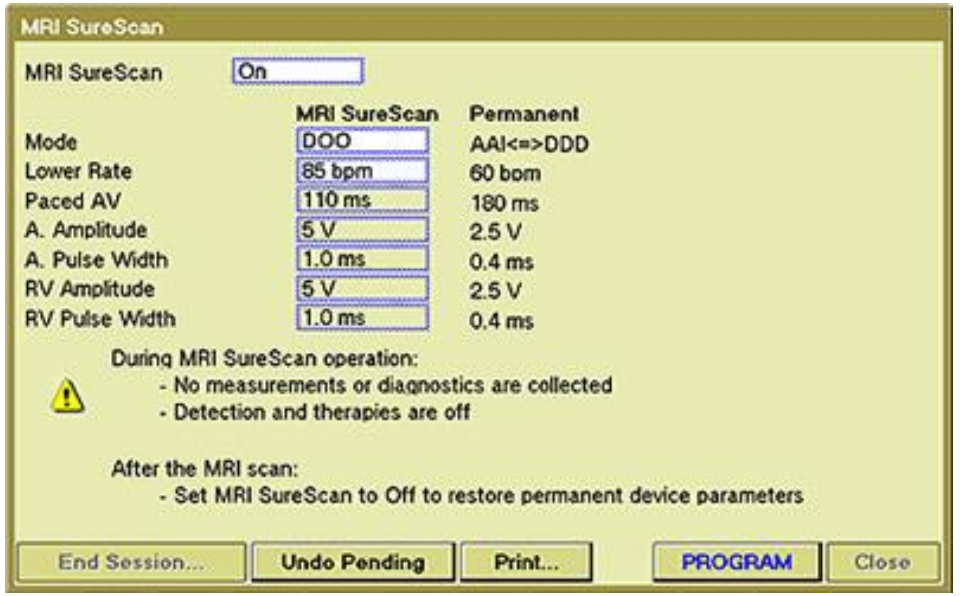
University of Chicago: Moyer D et al HRS Scientific Sessions 2018

- 18 Mismatched devices and leads
- No difference in performance (as compared to matched MRI-conditional and Non-conditional)


Medtronic
Advisa DR MRI™ SureScan™
RA
RV
IS-1
IS-1
TYPE DDDR
MODEL L301
ACCOLADE™
Boston Scientific
S (A/V)
ST. JUDE MEDICAL™
BE
ASSURITY MRI™
PM1272 SSIR
S/N 1234567
Edora 8 DR-T
Home Monitoring
DDDR
68507734
BIOTRONIK
Made in Germany
A
V
IS-1

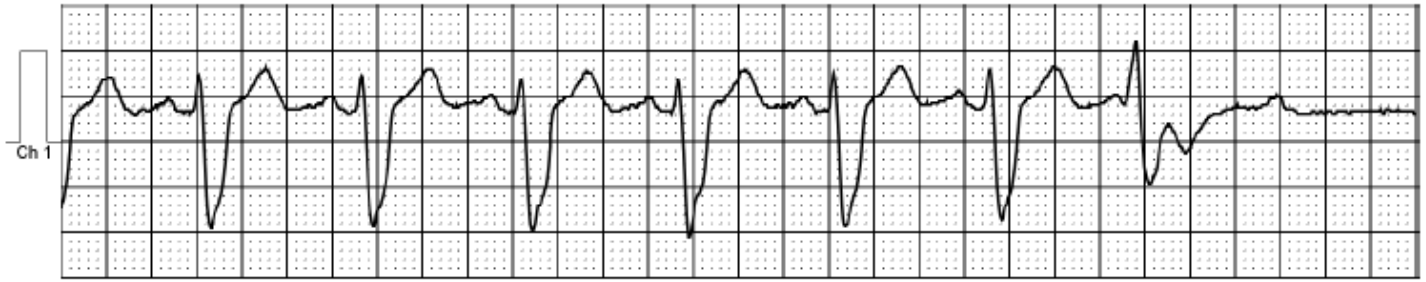
MRI–Conditional CIEDs
“Recommended” Programming



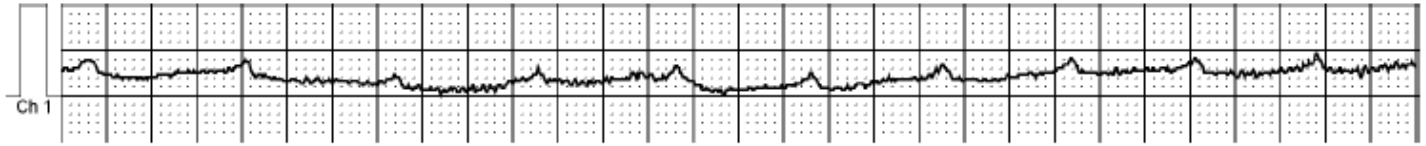


“For patients who do not require pacing support, program the device to the non-pacing mode (ODO for DR devices and OVO for SR devices)”
- Medtronic Academy

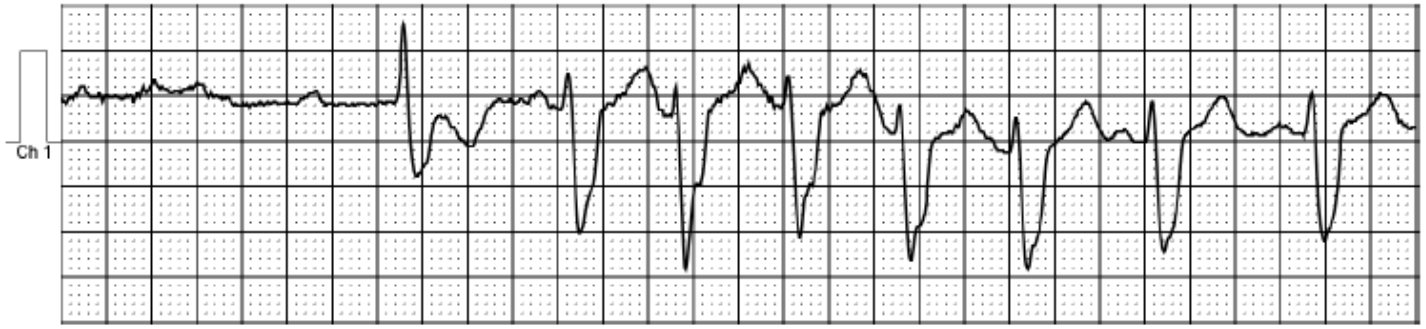
Automatic Event	09/20/2014 10:43:40 CDT	
Preliminary Findings	HR 80 bpm	Activities: None Indicated
Urgent - Sinus Arrhythmia with IVCD PVC and Ventricular Standstill Lasting 8.7 Seconds Onset, DR. SANDLER Notified 09/20/2014 09:19:09 PDT		Symptoms: Automatic Event



Automatic Event	09/20/2014 10:43:46 CDT	
Preliminary Findings	HR 0 bpm	Activities: None Indicated
Urgent - Ventricular Standstill Lasting 8.7 seconds, DR. SANDLER Notified 09/20/2014 09:19:09 PDT		Symptoms: Automatic Event



Automatic Event	09/20/2014 10:43:52 CDT	
Preliminary Findings	HR 70 bpm	Activities: None Indicated
Urgent - Ventricular Standstill Lasting 8.7 Seconds Offset into Sinus Rhythm with IVCD , DR. SANDLER Notified 09/20/2014 09:19:09 PDT		Symptoms: Automatic Event

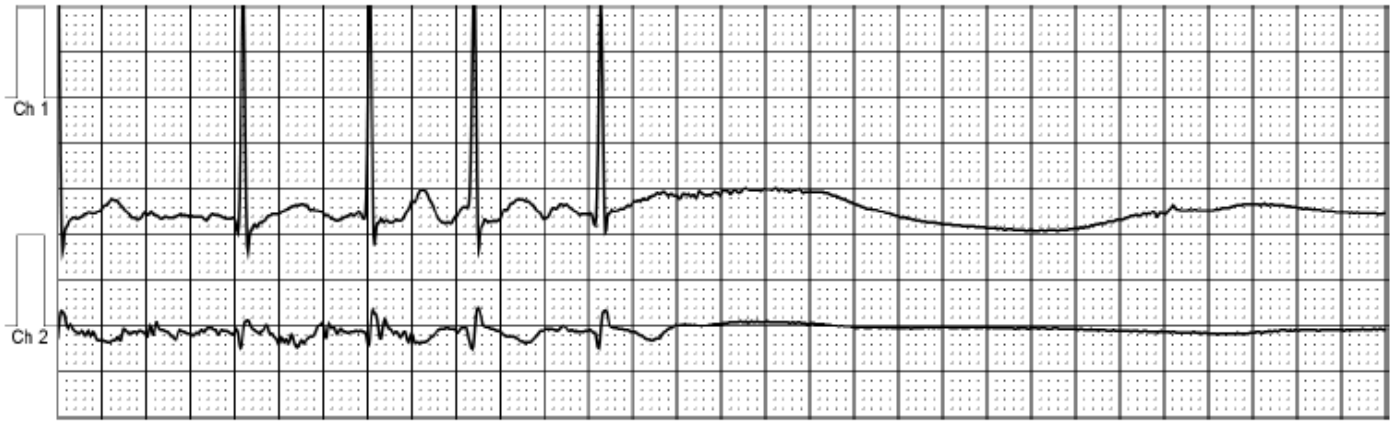


Time: 02/12/2013 17:31:30 CST

HR: 98

Automatic Trigger

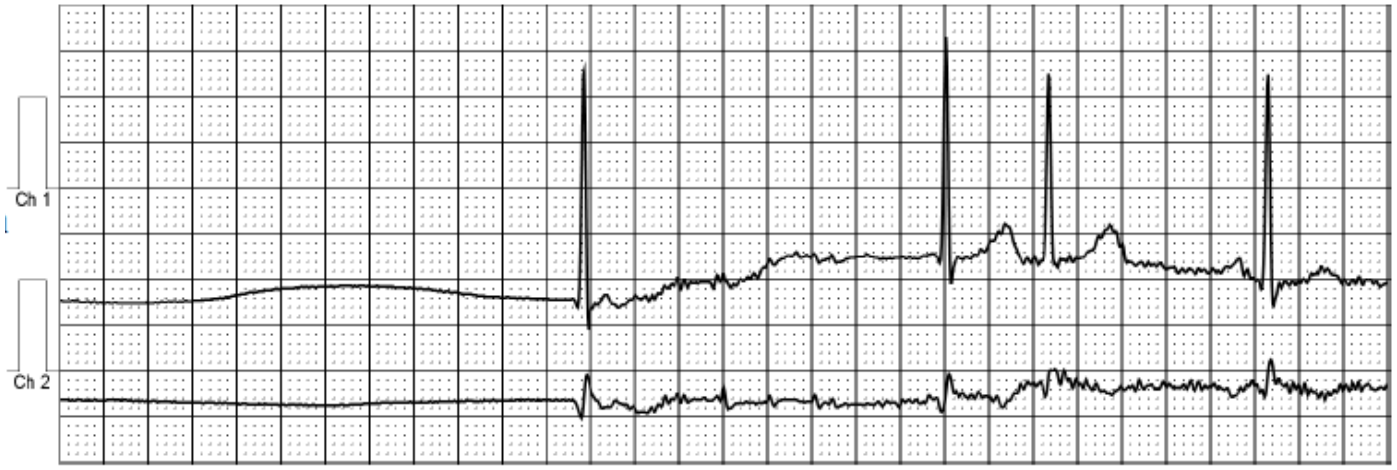
Findings: Urgent - Atrial Fibrillation/Flutter with 5.9 Second Pause Onset, Dr. Sandler notified on 2/12/2013 at 16:05 PST



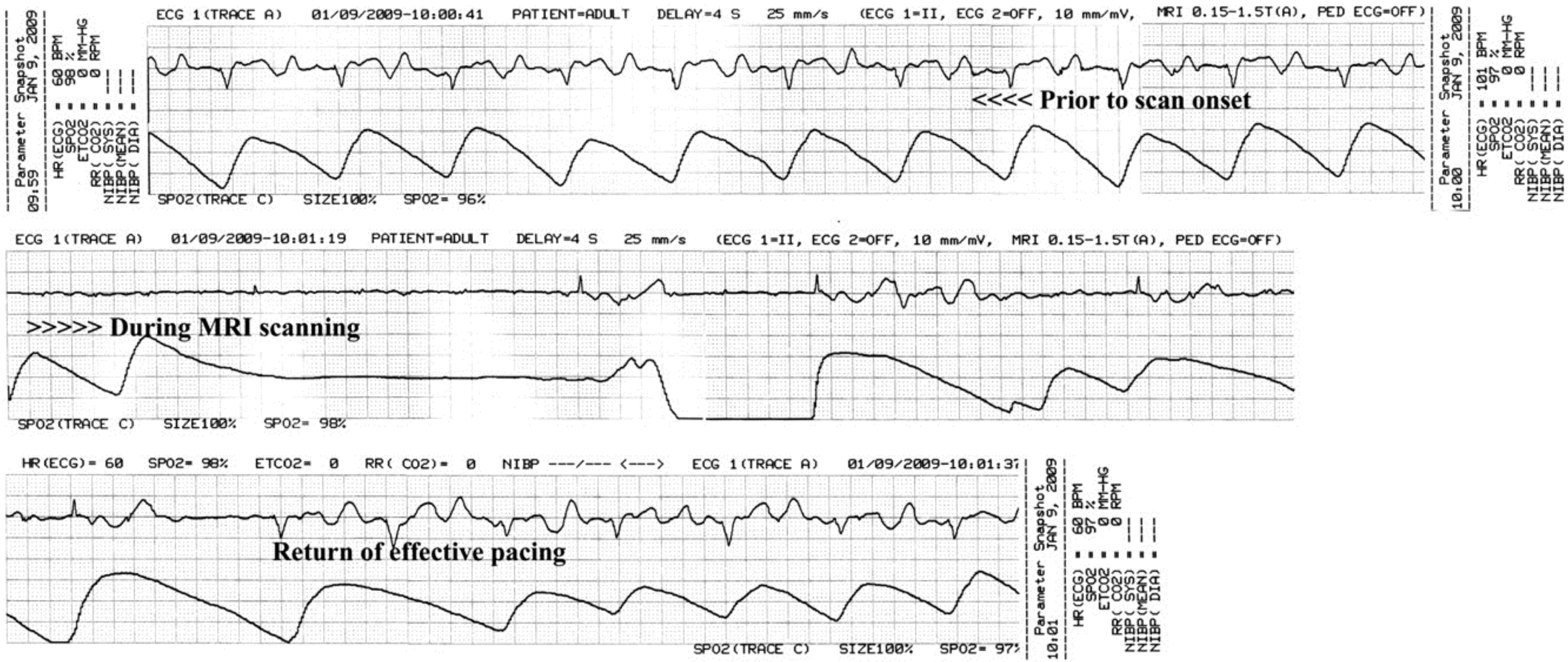
Time: 02/12/2013 17:31:36 CST

HR: 57

Automatic Trigger



The Risk of “Power-On Reset”



Gimbel JR *EP Europace*, 2009;11(9):1241–1242

2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices

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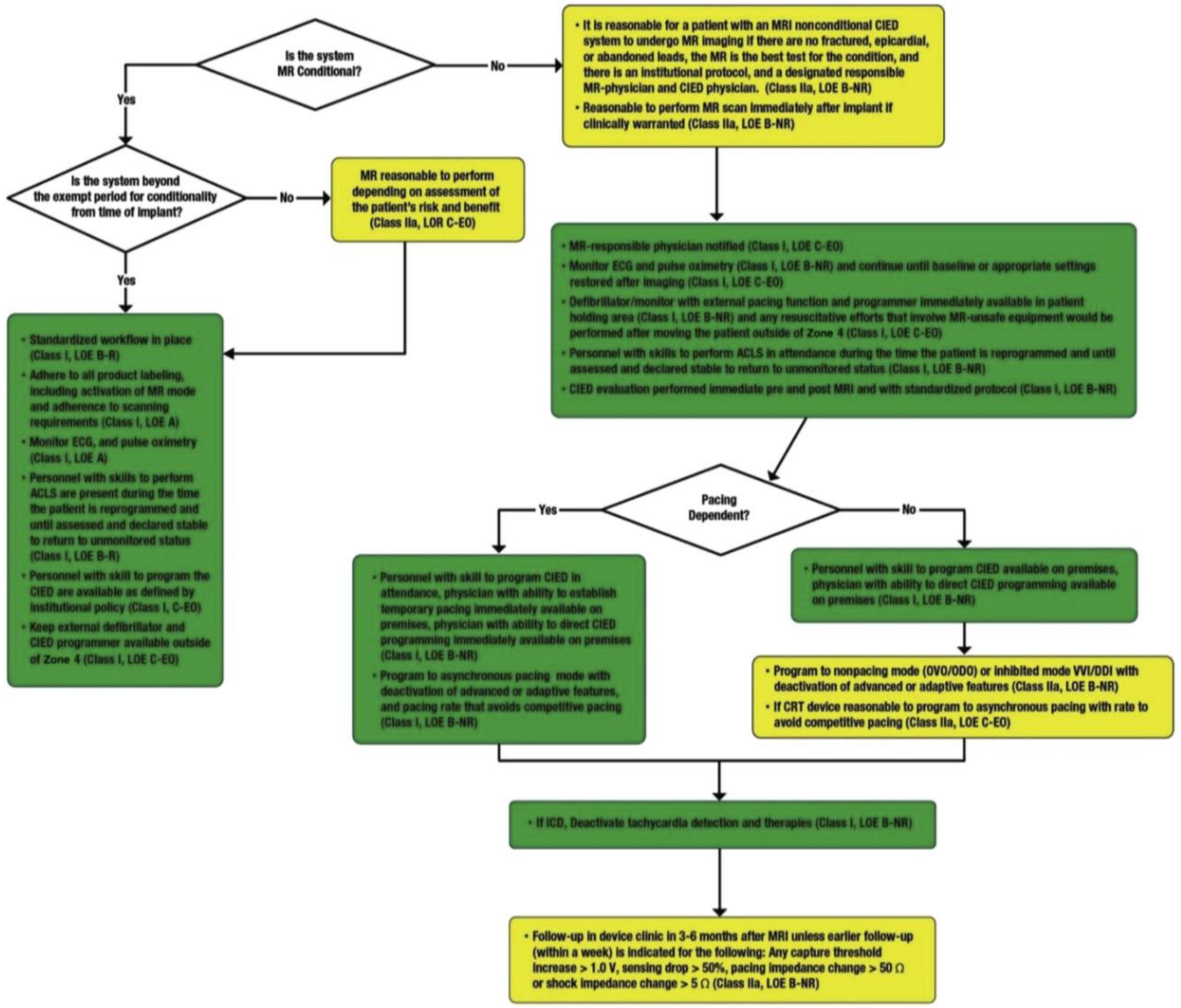
KEYWORDS Magnetic resonance imaging; Computed tomography imaging; Radiation therapy; Cardiac pacemakers; Implantable cardioverter defibrillators

ABBREVIATIONS **CIED** = cardiac implantable electronic device; **COR** = Class of Recommendation; **CRT** = cardiac resynchronization therapy; **CRT-D** = cardiac resynchronization therapy with implantable cardioverter-defibrillator; **CRT-P** = cardiac resynchronization therapy-pacemaker; **CT** = computed tomography; **dB/dt** = time-varying magnetic field; **DFT** = defibrillation threshold test; **ECG** = electrocardiogram; **EMI** = electromagnetic interference; **EO** = expert opinion; **EP** = electrophysiology; **ERI** = elective replacement interval; **FDA** = Food and Drug Administration; **Gy** = Gray, a measurement of absorbed radiation dose; **HR** = heart rate; **ICD** = implantable cardioverter defibrillator; **ILR** = implantable loop recorder; **LD** = limited data; **LINAC** = linear accelerator; **LOE** = Level of Evidence; **MR** = magnetic resonance; **MRI** = magnetic resonance imaging; **ms** = milliseconds; **MV** = megavolt; **mV** = millivolts; **NMR** = nuclear magnetic resonance; **NR** = nonrandomized; **PM** = pacemaker; **POR** = power-on reset; **R** = randomized; **RCT** = randomized controlled trial; **RF** = radiofrequency; **RT** = radiation treatment; **SAR** = specific absorption rate; **T** = Tesla, a measurement of magnetic field strength; **V** = volts; **VT** = ventricular tachycardia (Heart Rhythm 2017;14:e97–e153)

Developed in collaboration with and endorsed by the American College of Cardiology (ACC), American College of Radiology (ACR), American Heart Association (AHA), American Society for Radiation Oncology (ASTRO), Asia Pacific Heart Rhythm Society (APHRS), European Heart Rhythm Association (EHRA), Japanese Heart Rhythm Society (JHRS), Pediatric and Congenital Electrophysiology Society (PACES), Brazilian Society of Cardiac Arrhythmias (SOBRAC), and Latin American Society of Cardiac Stimulation and Electrophysiology (SOLAECE) and in collaboration with the Council of Affiliated Regional Radiation Oncology Societies (CARROS). **Address reprint requests and correspondence**: Heart Rhythm Society, 1325 G Street NW, Suite 400, Washington, DC 20005. E-mail address: clinicaldocs@hrsonline.org.

 http://dx.doi.org/10.1016/j.hrthm.2017.04.025



OHI Protocol

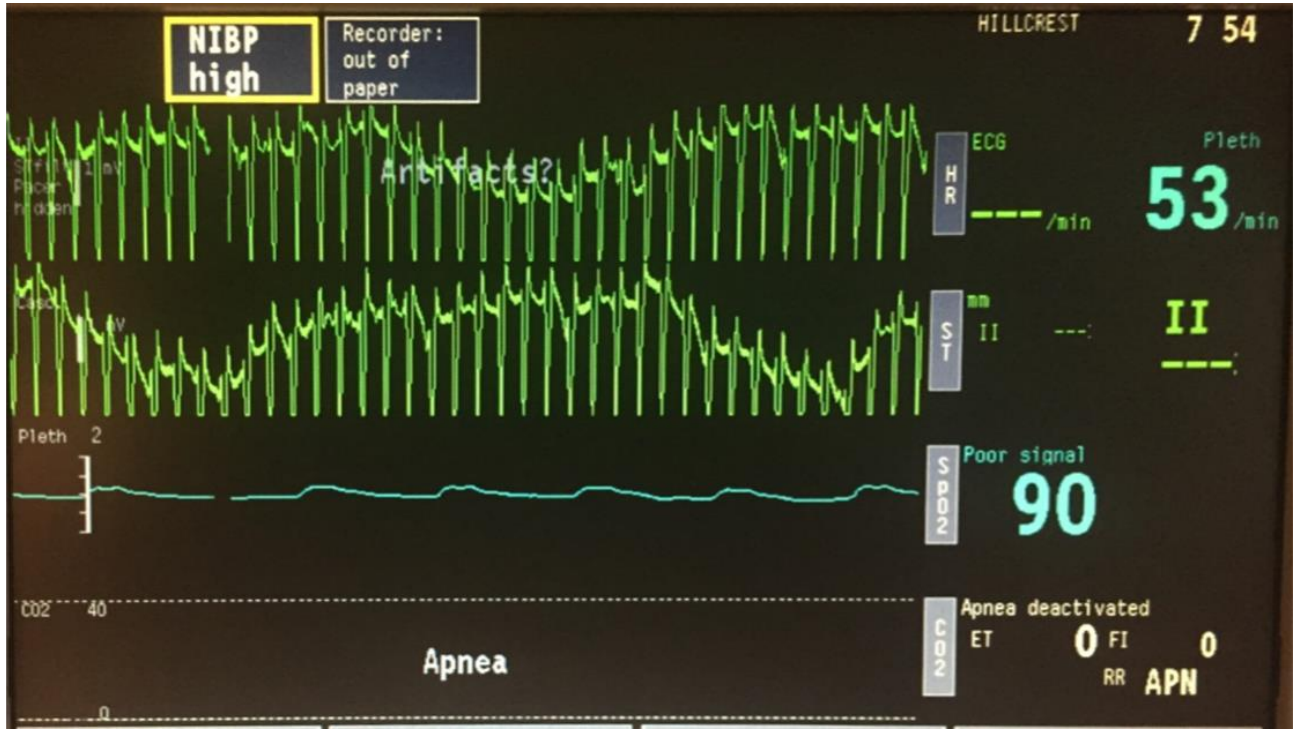
Pre-MRI

- EP Consulted
- Risks/Benefits Evaluated
- Programming “Prescription” Documented
  - Tachy-therapies OFF on all ICDs
  - Pacemaker Dependent: VOO/DOO
  - Non-Dependent: ODO, OVO, DDD, VVI, AAI
  - If not turning pacing off, remember to disable goofy algorithms

In MRI

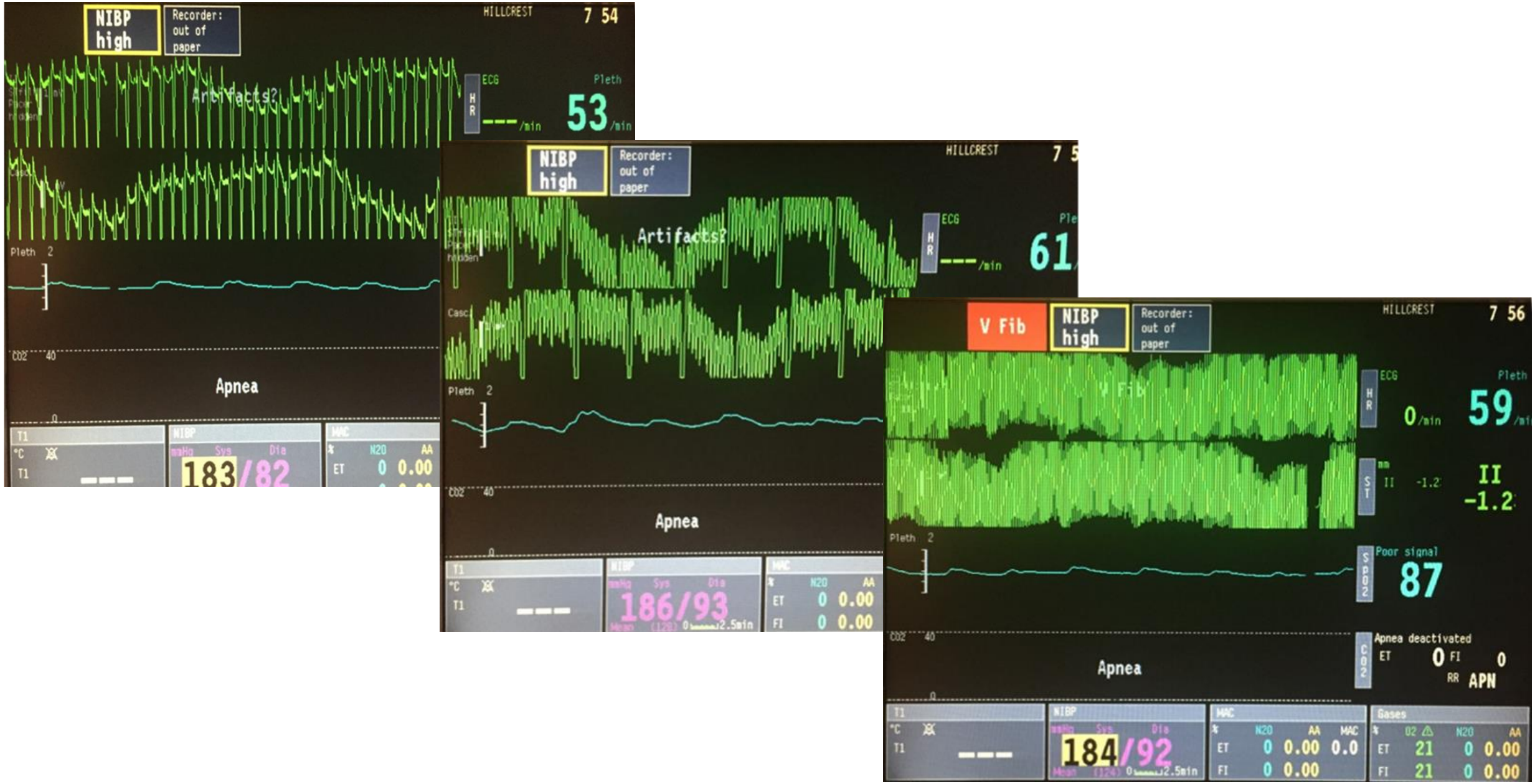
- MRI conditional/non-conditional treated essentially the same
- Device interrogated and programmed pre and post (w/thresholds)
- ACLS provider monitors throughout: Telemetry and pulse oximetry

During a Pacemaker MRI Allyson Sees This:



What Should Ally Do?

1. Run in and give adenosine
2. Run in with a defibrillator
3. Stop the MRI immediately
4. Keep sipping her coffee

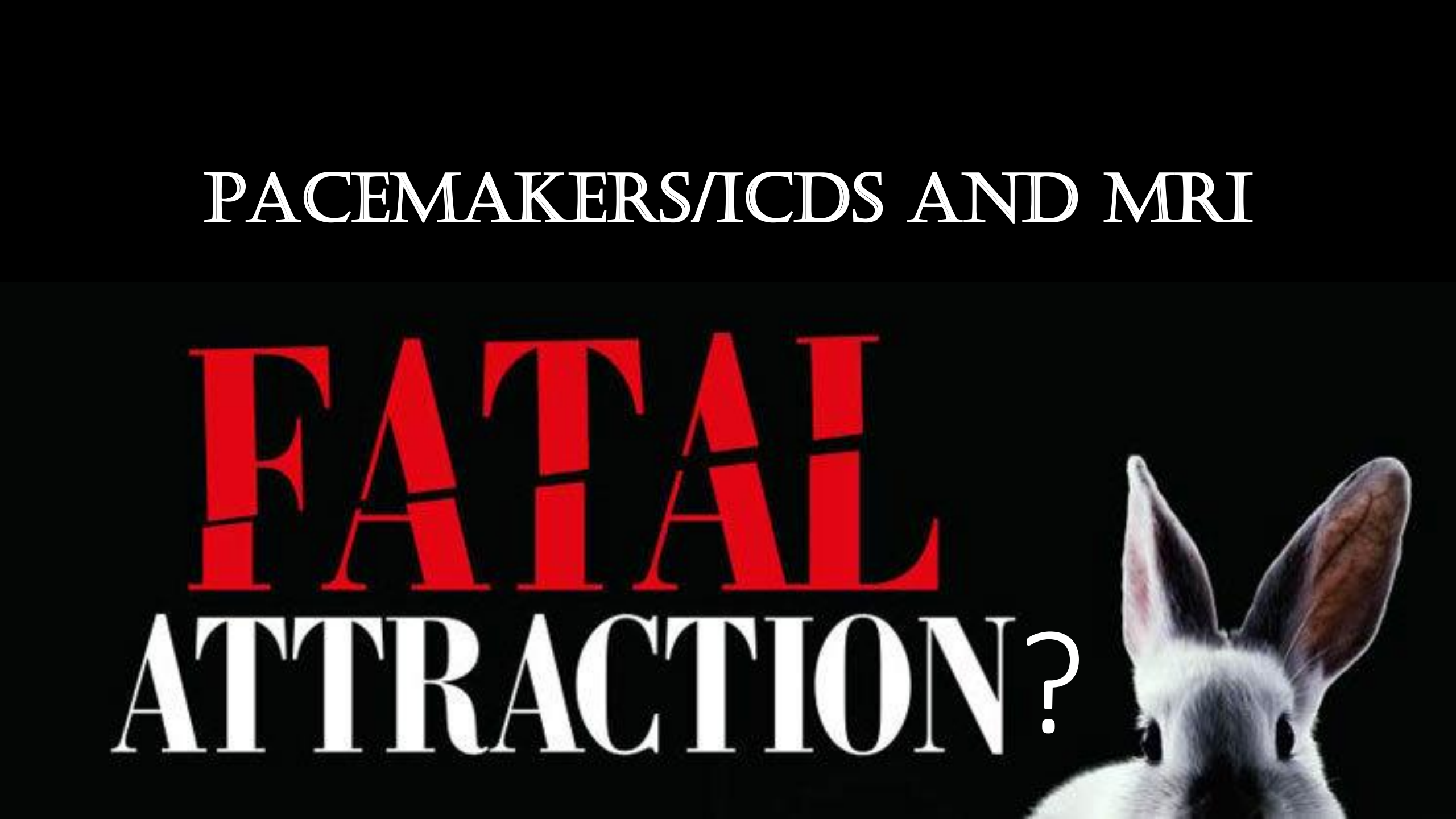

NIBP high
Recorder: out of paper
HILLCREST
7 54
Artifacts?
ECG
Pleth
53 /min
Pleth 2
CO2 40
Apnea
T1
NIBP
183/82
MAC
ET 0 0.00
NIBP high
Recorder: out of paper
HILLCREST
Artifacts?
ECG
61
Pleth 2
Apnea
186/93
ET 0 0.00
FI 0 0.00
V Fib
NIBP high
Recorder: out of paper
HILLCREST
7 56
V Fib
ECG
Pleth
0 /min
59
ST
II -1.2
Pleth 2
Poor signal
87
Apnea
Apnea deactivated
ET 0 FI 0
RR APN
T1
NIBP
184/92
MAC
ET 0 0.00 0.0
FI 0 0.00
Gases
ET 21 0 0.00
FI 21 0 0.00

Conclusion

- Most patients with pacemaker and ICDs may undergo MRI safely in a controlled, supervised environment
- CMS now recognizes (pays for) MRI when performed under protocol
- Careful attention is required to program the devices appropriately for the scan
- MR-conditional devices are available, but still require thoughtful programming and monitoring

Still Contraindicated….

PACEMAKERS/ICDS AND MRI



Pacemaker/ICDs and MRI
Fatal Attraction?

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References

HRS Guidelines:

- Indik JH et al *Heart Rhythm* 2017;14(7): e97-e153

CMS Decision Memo: 4/2018

- CAG-00399R4