CIEDs in MRI environment current practice and future developments

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JERUSALEM


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HAIFA

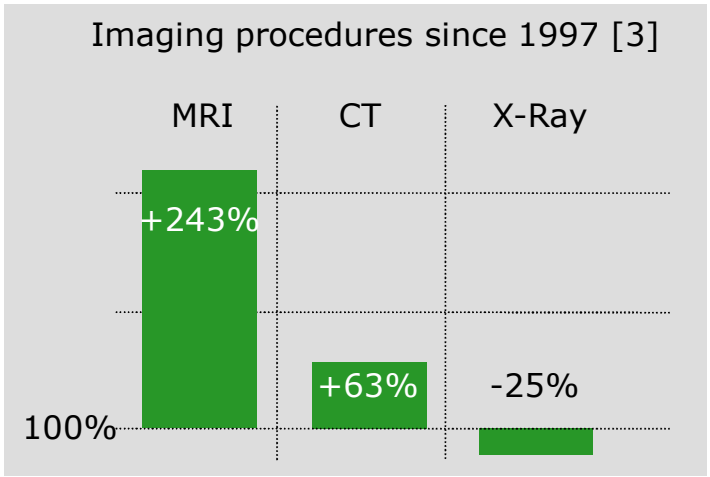

DEAD SEA

The Leviev Heart Center

Access to MRI.

Development of imaging procedures

- 50-75% of patients with a cardiac device are indicated for an MRI scan [1]
- 17% of pacemaker patients need an MRI within 12 months after implantation [2]



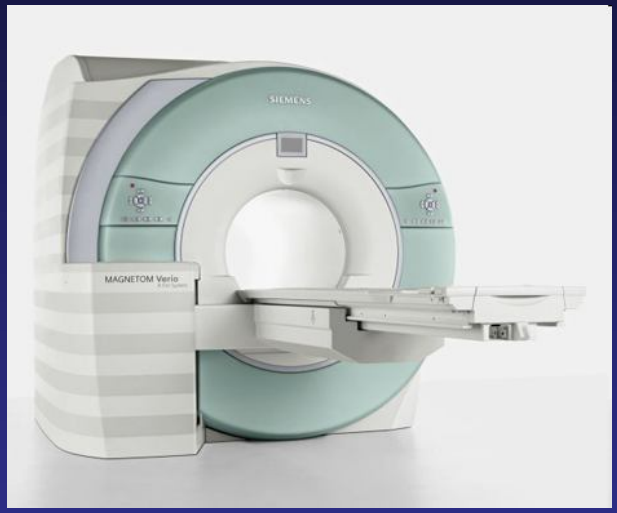
[1] Kalin et al.; Current clinical issues for MRI scanning of pacemaker patients; PACE 2005; 28: 326–328

[2] Martin et al.; MRI and Pacemaker Safety; JACC 2004; Vol. 43, No. 7: 1315–24.

[3] Scientific Institute AOK; 3/2010

What is MRI?

Three major components of MRI-Scanners relevant to CIEDs:



- Static magnetic field
- Radio frequency (RF) fields
- Gradient magnetic fields

Potential Effect of MRI on CIEDS

- Static magnetic field (always-on, 1.5- 3 TESLA)
  - Reed switch closure (asynchronous pacing , arrhythmia detection suspended)
  - Generator Displacement
- Pulsed RF field (SAR) + Time – varying magnetic fields
  - Induction of electrical currents in leads
  - Inhibition or triggering of pacing including rapid rate -> VF
  - Spurious tachyarrhythmia detection by ICD
  - Heating by antenna effect (tissue damage , thresholds , VF)
  - Electrical reset
  - Circuit damage

Preliminary reports of events

- At least 10 cases of death during scan in PM pts so far
- FDA database reports of death of CIED pts in MRI [1]
- 6 deaths reported from Germany (3 VF) [2]
- All reported severe clinical events occurred with inadvertent patient exposure to MRI without preparation / monitoring

1-FDA guidance document
2- Irnich Europace 2005

Risk Factors for Serious Events

- Device age
- Chest MRI
- Total dependence
- Repeated exposures
- Static magnetic field >1.5 TESLA
- RF power > 2W/kg
- Abandoned /fractured/epicardial leads(heating)
- New (<6 weeks) or free floating leads

Europace (2008) 10, 336–346
doi:10.1093/europace/eun021

EUROPEAN SOCIETY OF CARDIOLOGY®

POSITION PAPER

Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices

Ariel Roguin[1]*, Juerg Schwitter[2], Christian Vahlhaus[3], Massimo Lombardi[4], Josep Brugada[5], Panos Vardas[6], Angelo Auricchio[7], Silvia Priori[8], and Torsten Sommer[9]

AHA Scientific Statement

Safety of Magnetic Resonance Imaging in Patients With Cardiovascular Devices

An American Heart Association Scientific Statement From the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention

The Sheba Protocol for MRI Scanning in CIED patients

- Clinic visit prior to MRI
  - Verify the need , risk stratify and explain risk to pt and referring MD (reconsider if dependent)
  - Information on all implanted / old/ abandoned hardware
  - Confirm normal function and thresholds
  - Note high risk situations
  - Prescribe programming for MRI exam

The Sheba Protocol for MRI Scanning in CIED patients

- Programming :
  - ICD detection off
  - Dependent patients asynchronous mode at high output (not available in some ICD models)
  - Nondependent patients in OOO or low output low rate pacing
  - Rate response magnet response PVC response triggering , noise reversion all OFF
  - High output for one month , then clinic follow up

The Sheba Protocol for MRI Scanning in CIED patients

- During scan :
  - Pacemaker technician and ACLS proficient nurse present , pacemaker MD available
  - Crash cart and monitoring (oxymetry!)
  - Minimal duration and exposure
  - Full device check prior to and after scan , high output programming on discharge for one month

The Sheba Experience

- 114 scans in 75 patients
- 16 pts with 2-15 scans each
- 74 brain, 20 spine , 20 miscellaneous
- Results:
  - 10 Power-On Reset
  - 1 irreversible ERI (replaced)
  - 1 case of Loss of Capture + low impedance (replaced)

Halstock,,, Glikson,,, IMAJ 2010

Annals of Internal Medicine | ORIGINAL RESEARCH

A Prospective Evaluation of a Protocol for Magnetic Resonance Imaging of Patients With Implanted Cardiac Devices

Saman Nazarian, MD; Rozann Hansford, RN, MPH; Ariel Roguin, MD, PhD; Dorith Goldsher, MD; Menekhem M. Zviman, PhD; Albert C. Lardo, PhD; Brian S. Caffo, PhD; Kevin D. Frick, PhD, MA; Michael A. Kraut, MD, PhD; Ihab R. Kamel, MD, PhD; Hugh Calkins, MD; Ronald D. Berger, MD, PhD; David A. Bluemke, MD, PhD; and Henry R. Halperin, MD, MA

- 438 pts (46% ICDS) underwent 555 MRI studies
- 0.7% reversion to backup mode
- No severe adverse events
- No need for any device revision
- Reviewed additional 656 cases reported in the literature without severe events

Ann Intern Med 2011

Magnasafe Registry- HRS 2012

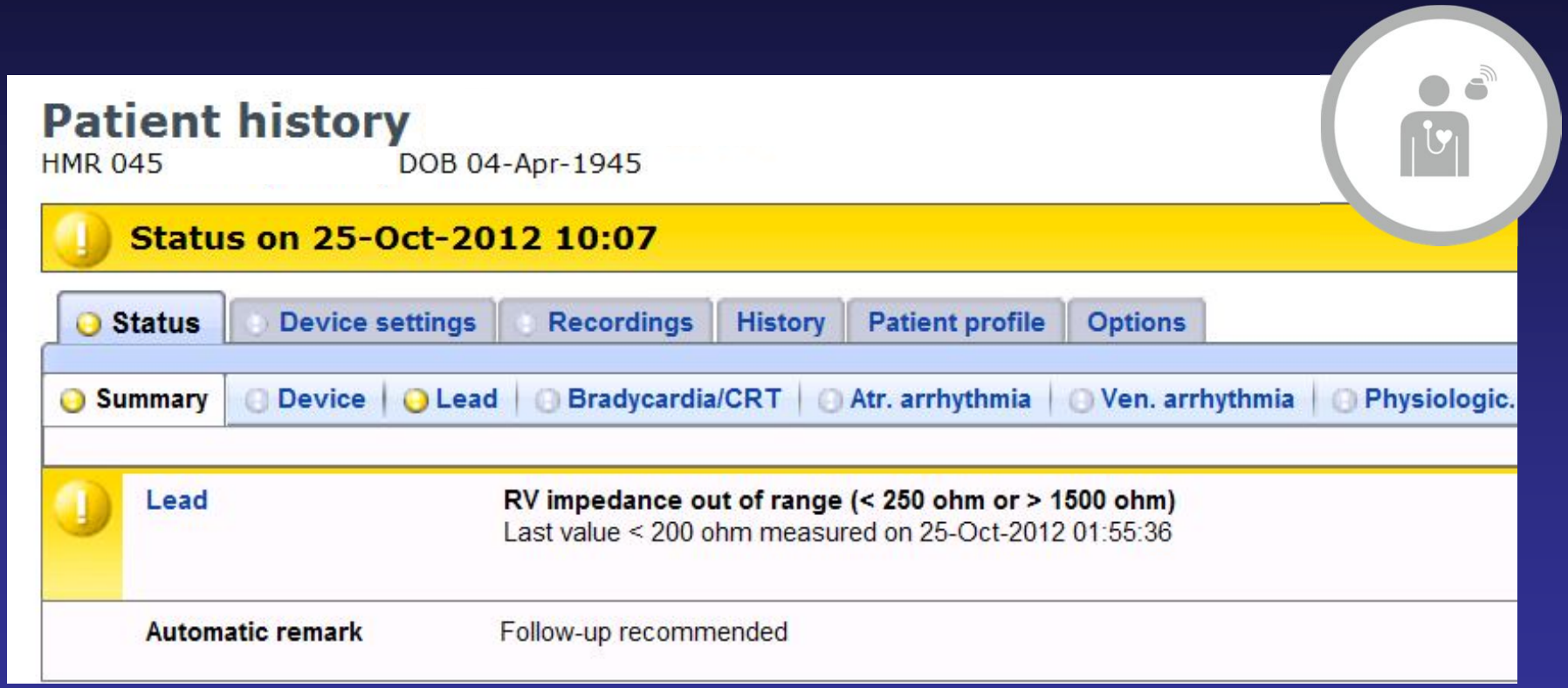
- N = 500 (planned 1500) non-MRI devices
- Reversion to backup mode (2)
- Mild decrease in battery voltage
- No serious adverse events or damage to device

A Case Study

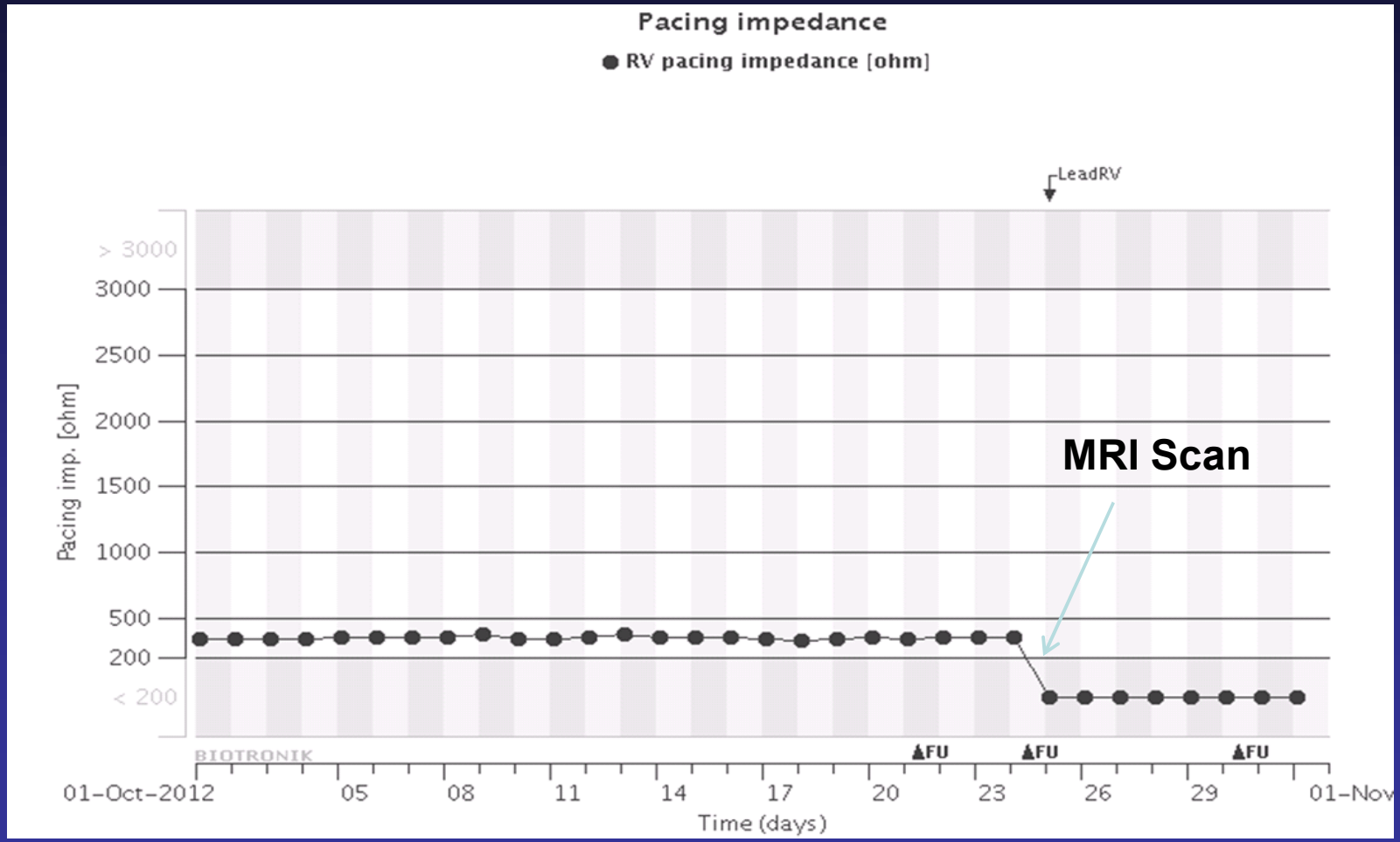
- A 67 yo man with dilated CMP and recurrent slow VTS
- Biotronik Lumax VR – T ICD implanted 2011 on Kentrox lead (implanted 2006)
- Has partially resected pituitary adenoma has had 6 MRIS over three years (two with current device)
- Underwent another scan on 20/10/12 with normal testing before and AFTER scan

Alert Triggered Virtual Follow Up

Via Home Monitoring



Device or Lead Related?



Manual in-clinic follow up

- Pacing impedance: < 200 ohm
- Pacing threshold: non-capture
- Sensing: intact

Dillemas

- Is it a lead damage ? PG damage ?
- Related to MRI?
- What should be done at this point :
  - Test system at replacement , consider replacing the lead only and avoid further MRIs (operate ?)
  - New MRI conditional ICD system **and old lead extraction**

New MRI Conditional CIED Systems

- Reduction of ferromagnetic components
- Protection circuits in hardware
- Component arrangement and material combination to avoid circuitry damage
- Different lead structure

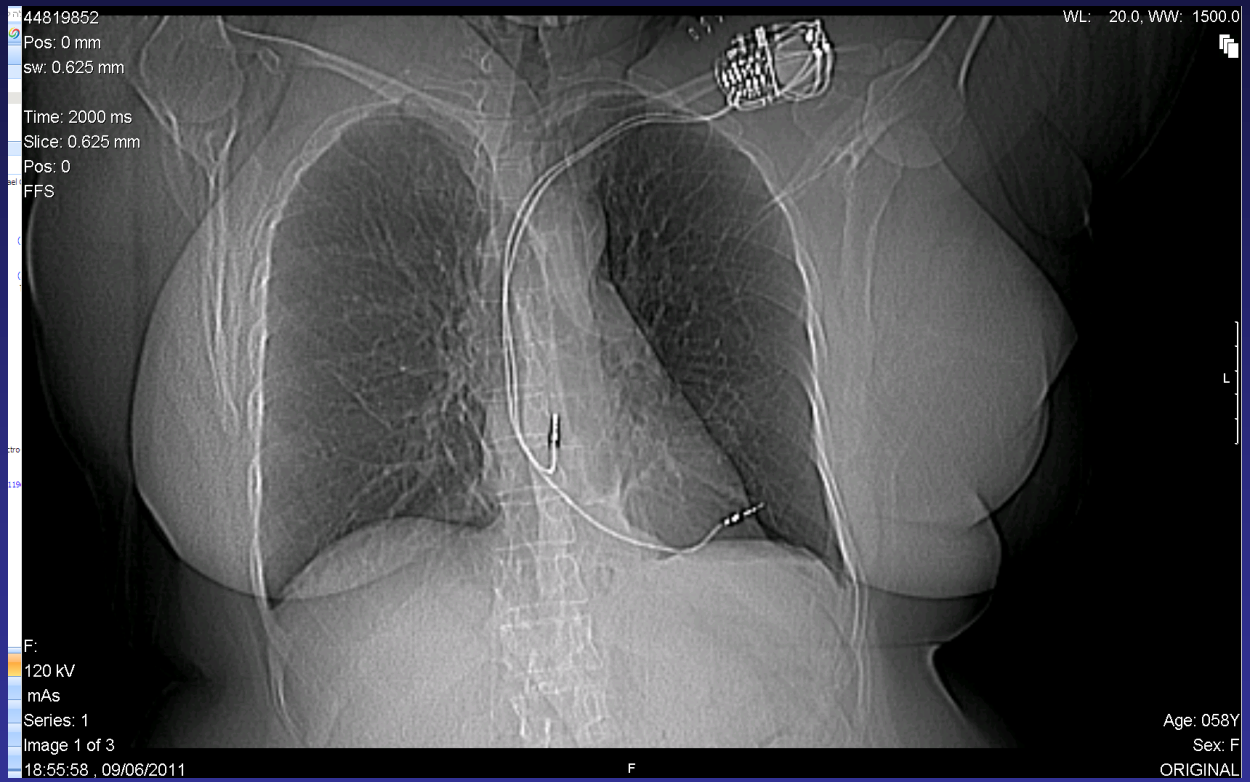
- Dedicated programs for scanning

History of MRI Conditional CIEDS

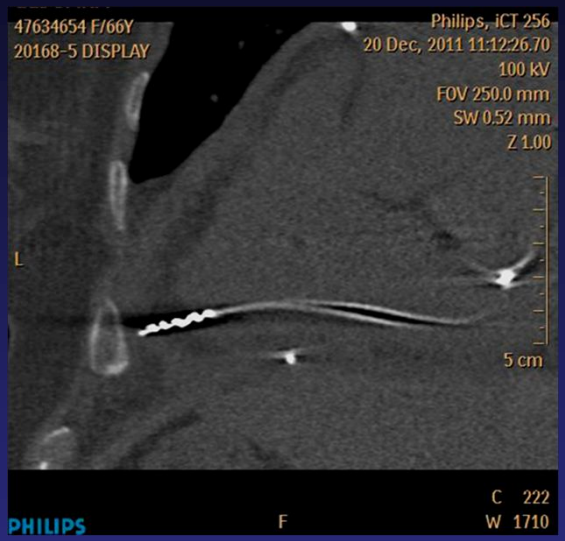
- Medtronic Surescan ™ pacing system (Enrythm + 5086 screw-in leads)
- Surescan study published 2011 (464 pts)[1]
- FDA approval
- Second generation MRI conditional systems with no limitation on chest scanning
- Additional pacemakers (SJM, Biotronik)
- Biotronik first MRI conditional full line of pacing products and ICDs

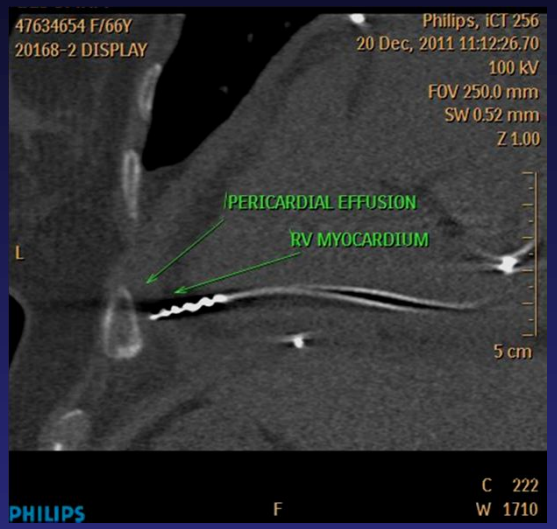
1- Wilkoff et al , HRJ 2011

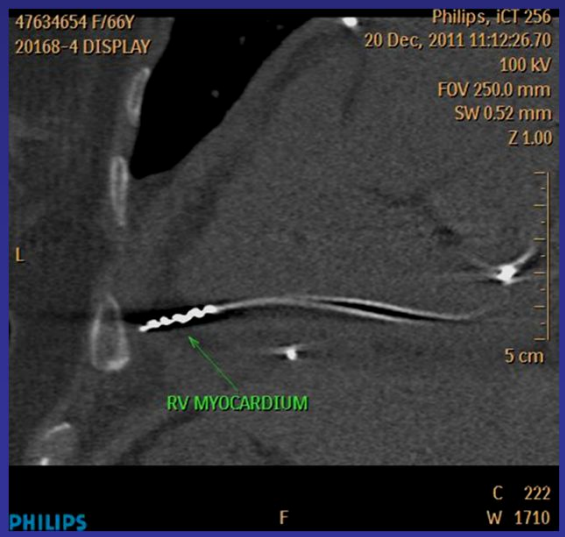
A Patient with 5086 leads

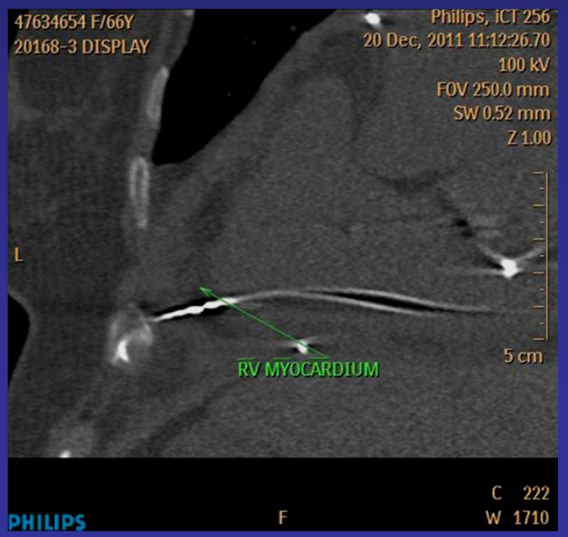


One day following 5086 Implantation

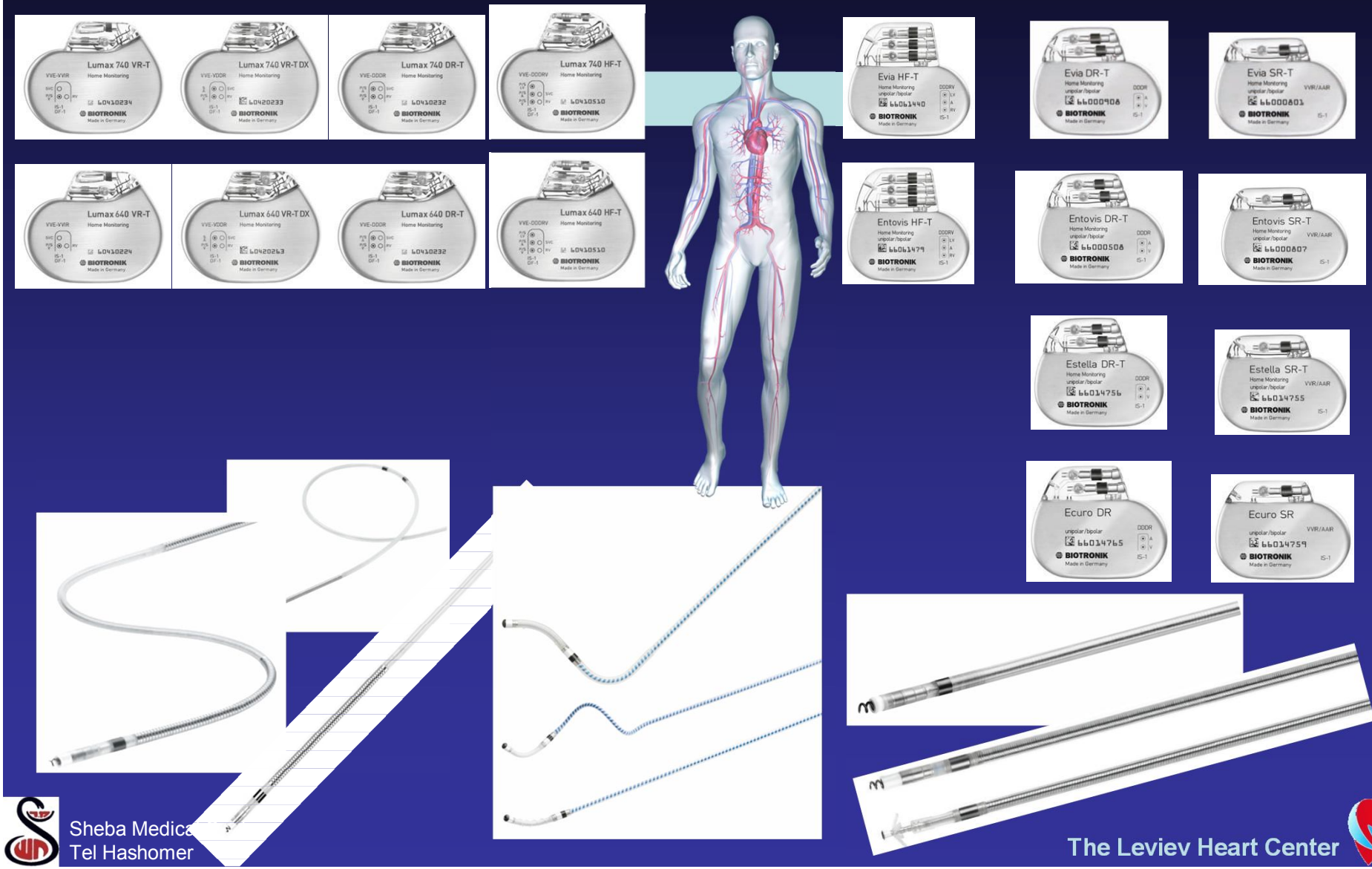








Biotronik MRI Conditional Line



Monocenter feasibility study of the MRI compatibility of the Evia pacemaker in combination with Safio S pacemaker lead

Journal of Cardiovascular Magnetic Resonance 2012, 14:67 doi:10.1186/1532-429X-14-67

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- 31 pts with MRI conditional pacing system
- 50% DDD 50% VVI
- All underwent MRI
- No serious adverse events
- No changes in device function

ProMRI® - Guidance

Checklist-guided programming supports keeping the right conditions

MRI checklist

Check device and leads

- A dedicated BIOTRONIK MR conditional lead and pacemaker form an MRI-tested system
- Device has been implanted in the pectoral region for more than 6 weeks
- Follow-up was successful and threshold does not exceed 2.0 V at 0.4 ms
- No additional active medical devices present
- No additional leads, wire adapters or lead extenders present

Radiological considerations

- Standard 1.5 T cylindrical scanner architecture required
- Continuous patient monitoring required during MR scan
- Observe specific conditions for MR Conditional devices (SAR, scan zone, field strength ...)
- After MRI scan, restore previously programmed parameters, program and confirm settings.

MRI mode	V00
Basic rate [bpm]	90

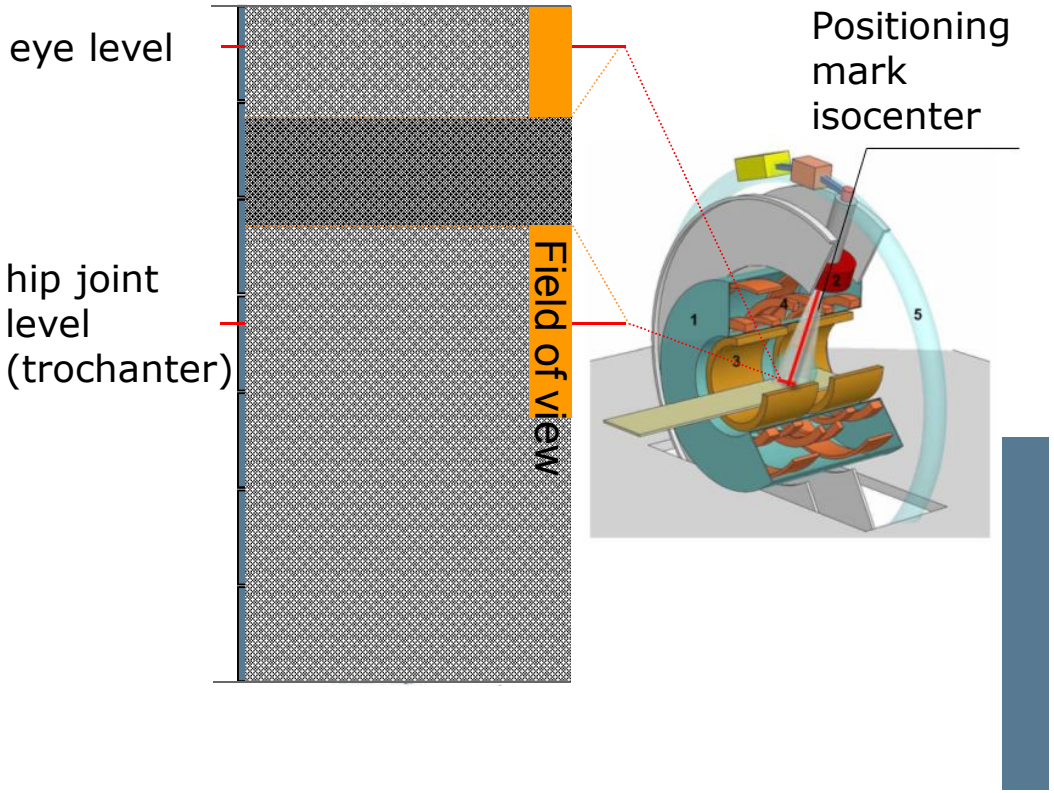
☑ **I accept the conditions for MRI examinations**

- Please select an MRI mode. After clicking 'OK' the MRI parameters will be displayed.
- Selecting 'Program' on the next screen will program the implant accordingly.
- Any parameter change will result in the loss of the MRI program.

Print | Help | | OK | Cancel

ProMRI® procedure
Simple and straightforward

Some MR Conditions of BIOTRONIK



* Patient length: 1.75 m
Field of view: 50 cm*
The field of view is the visible scan area around the isocenter which size is defined by the MRI manufacturer

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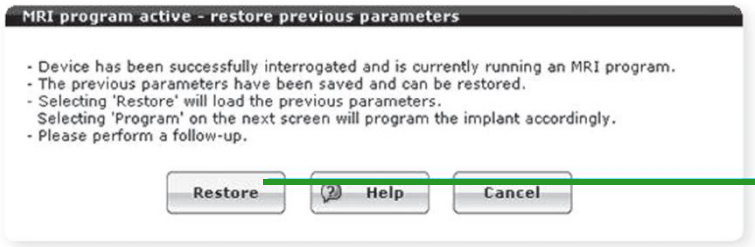
ProMRI® procedure
Simple and straightforward

Intuitive, step-by-step programming of MRI settings

After MRI scanning



Restore initial settings with just one click

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Conclusions

- MRI can be performed if necessary in patients with old type CIEDS with reasonable but not absolute safety , and with some medicolegal and administrative issues
- New MRI conditional pacemakers are available that provide better safety and nearly unlimited use of MRI
- Recent development of MRI conditional ICDs is a big step forward in the use of MRI in ICD pts

Future Research and Developments

- True effect of abandoned leads - is extraction really necessary ?
- Effect of cumulative exposure in multiple MRI scans
- Chest MRIs
- 3 Tesla MRIs
- Should we implant MRI conditional CIEDS in all patients ?

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12th International Dead Sea Symposium

24-27/2/14

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Terminology for Labeling CIEDs

Newer terminology	
MR safe	An item that poses no known hazards in any MR environment. Using the new terminology, "MR safe" items include nonconducting, nonmetallic, nonmagnetic items, such as a plastic Petri dish.
MR conditional	An item that has been demonstrated to pose no known hazards in a specified MR imaging environment with specified conditions of use. Conditions that define the MR environment include static magnetic field strength, spatial magnetic gradient, dB/dt (time-varying magnetic fields), RF fields, and SAR. Additional conditions, including specific configurations of the item (eg, the routing of leads used for a neurostimulation system), may be required.
MR unsafe	An item that is known to pose hazards in all MR environments. "MR unsafe" items include magnetic items such as a pair of ferromagnetic scissors.

Levine AHA Scientific Statement 2007

Rapid pacing by CIED

- Atrial sensing of EMI with rapid tracking (upper rate)
- Runaway tachycardia
- Voltage induction by time-varying magnetic fields (unrelated to programmed output or mode)

Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment

Bruce L. Wilkoff, MD, FHRS, CCDS,* David Bello, MD,† Milos Taborsky, MD, PhD, FESC,‡ Josef Vymazal, MD, PhD,‡ Emanuel Kanal, MD, FACR, FISMRM,§ Hubertus Heuer, MD,‖ Katrin Hecking, MD,‖ W. Ben Johnson, MD, CCDS,¶ William Young, MD,¶ Brian Ramza, MD, PhD,** Naveed Akhtar, MD,** Bernhard Kuepper, MD,†† Peter Hunold, MD,†† Roger Luechinger, PhD,‡‡ Helmut Puererfellner, MD,§§ Firat Duru, MD,‖‖ M.J.W. Gotte, MD,*** Richard Sutton, MD, PhD,††† Torsten Sommer, MD‡‡‡; on behalf of the EnRhythm MRI SureScan Pacing System Study Investigators

- 464 pts implanted with 1st generation surescan system
- 258 randomized to undergo MRI 9-12 weeks post implantation
- Limited to 1.5 T, avoidance of thorax, no abandoned leads, normal functioning systems , low thresholds
- Evaluated up to 1m following the scan
- There were no adverse events parameter or threshold changes as a result of MRI