



# L'imaging con Risonanza nel paziente con pacemaker ed ICD: è veramente finito un tabù ?



**Giovanni Bisignani**  
ASP Cosenza -Cardiologia -Castrovillari

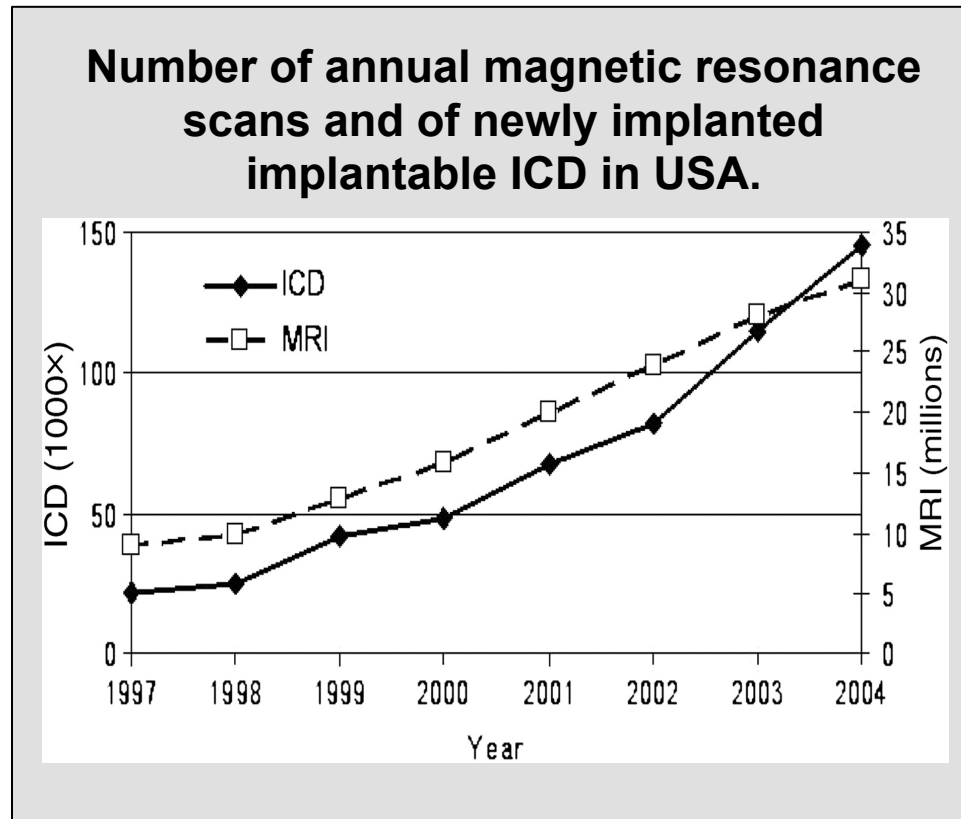


## **C'è la necessità di avere pacemakers o ICD MRI-safe**

- **No** se la risonanza non è utile o se ci sono test di imaging alternativi di facile esecuzione e sicuri
- **No** se non esiste rischio per il device e/ o per il paziente sottoposto a MRI

# MRI e DEVICE: due tecnologie che corrono insieme

> **60 milioni** di pazienti sottoposti a RM ogni anno

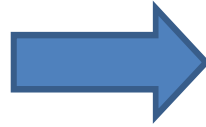


**1 milione** di dispositivi cardiaci impiantati ogni anno nel mondo

**Il 50-75%** dei pazienti impiantati necessitano di una MRI nel corso della vita del dispositivo

# Interazioni fra device e MRI

Campo Magnetico Statico  
 $B_0$  [Tesla]



**Effetto meccanico**  
Spostamento o torsione

Campi magnetici di Gradiente (~ kHz)  
 $dB/dT$  [T/m/s]



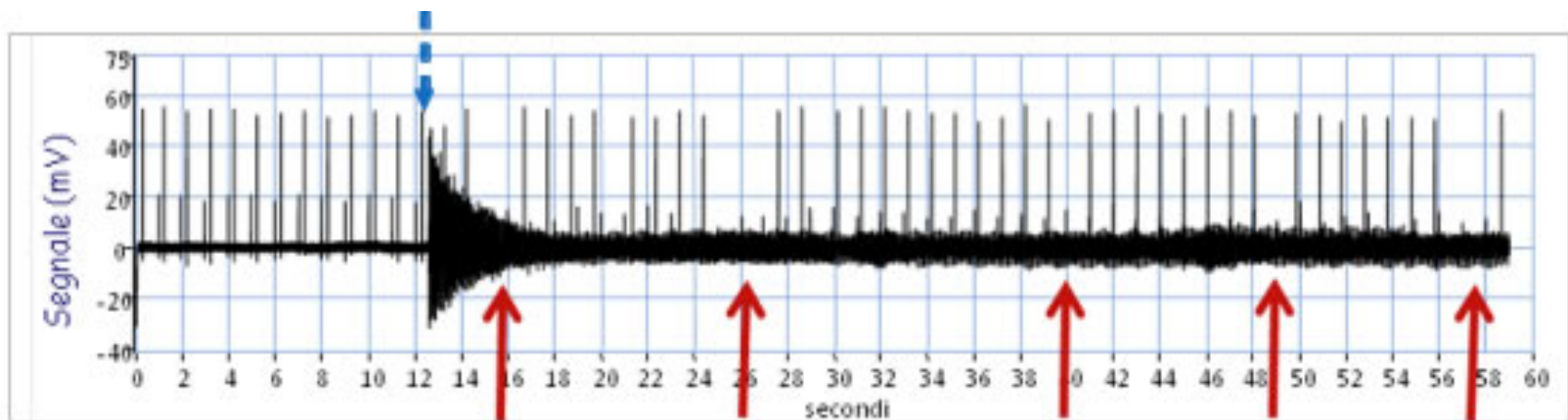
**Effetto interferente**  
Alterazioni del funzionamento del device

Campo elettromagnetico a radiofrequenza (~MHz)  
RF, SAR [W/Kg]

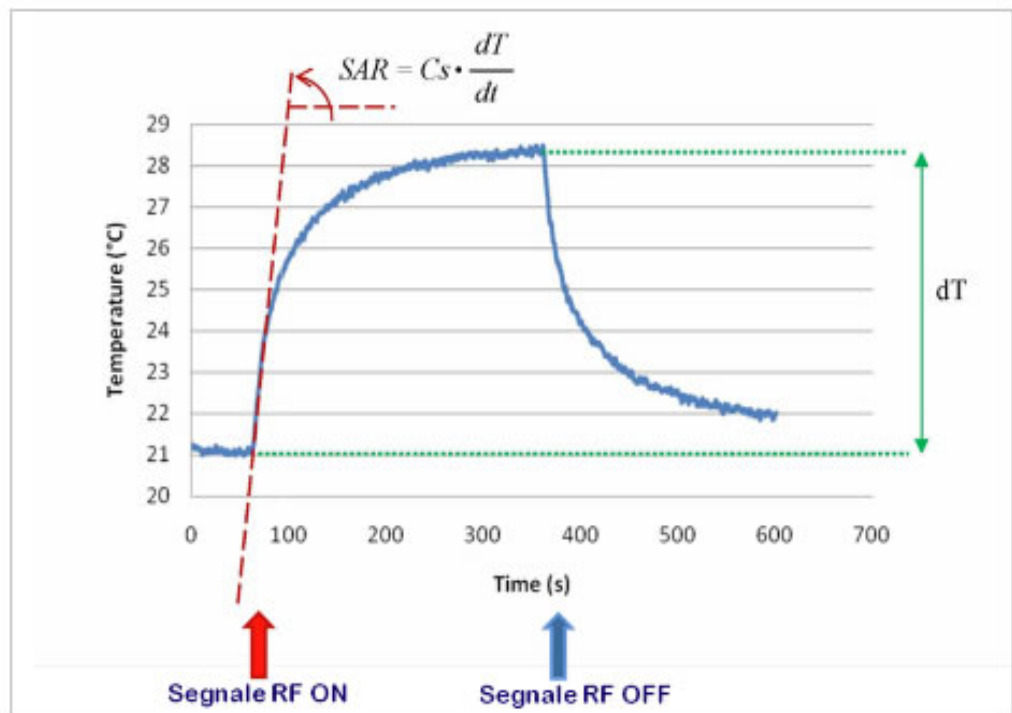


**Effetto pro-aritmico**  
Induzione di tensioni e correnti sui cateteri

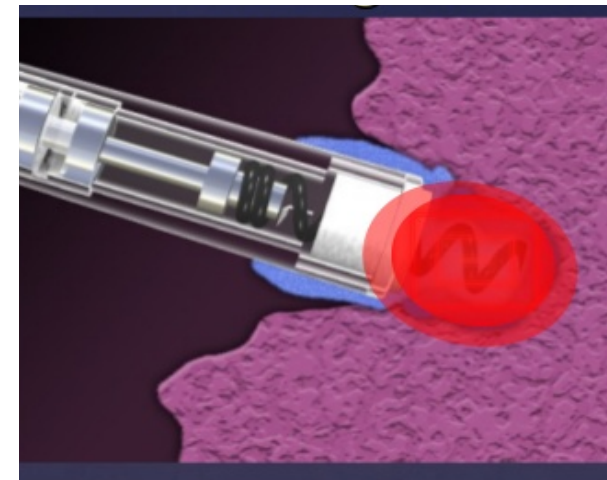
**Effetto termico**  
Riscaldamento sulla punta dell'elettrodo



**Figura 2.** Effetto del campo di gradiente su un impianto di pacemaker. In seguito all'attivazione dei campi di gradiente (freccia tratteggiata) il pacemaker si inibisce in alcuni istanti. [Dati raccolti dai ricercatori del Dipartimento Tecnologie e Salute, Istituto Superiore di Sanità]



**Figura 3.** Esempio dell'andamento della temperatura sulla punta dell'elettrocatteter in seguito all'attivazione del segnale a RF e al successivo spegnimento.



A causa di queste interazioni e delle potenziali conseguenze sul paziente, per un lungo periodo l'esecuzione di esami di risonanza magnetica è stata preclusa ai pazienti con device.

**DENIED**



# Ma i rischi sono reali ?

## The MagnaSafe Registry



The screenshot shows the heart.org website interface. At the top, there's a navigation menu with categories like ACS, Arrhythmia/EP, Brain/Kidney/Peripheral, Clinical cardiology, Heart failure, Hypertension, Imaging, Interventional/Surgery, Lipid/Metabolic, Prevention, and Thrombosis. The main article is titled "MRI of Implantable devices: Do we need safer devices, safer scanning procedures, or both?" dated March 18, 2010. The article text includes: "La Jolla, CA - Just as so many clinicians are cautioning clinicians against using MRI scans of patients with implantable cardiac devices until the 'true risk' of MRI scans of patients with implantable cardiac devices (pacemakers and defibrillators) is adequately studied. The MagnaSafe registry launched last spring will study about 125 of a planned 250 patients with ICDs; the primary outcome of device parameter changes." A quote from Dr. Robert Russo is highlighted in a box: "All of the concerns, for the most part, are almost hysterical concerns, and none of them are based on facts. Every kind of potential disaster that we've tried to research has all just ended up being an urban legend across the community or the literature." Below the quote is a photo of Dr. Robert Russo and his title: "MagnaSafe co-principal investigator Dr. Robert Russo (Scripps Clinic, La Jolla, CA)".

**the heart.org** Tuesday, May 15, 2010  
10 YEARS OF ONLINE CARDIOLOGY

**THE DAWN OF A NEW CLASS OF IMAGING AGENTS**

ACS    Arrhythmia/EP    Brain/Kidney/Peripheral    Clinical cardiology    Heart failure    Hypertension  
Imaging    Interventional/Surgery    Lipid/Metabolic    Prevention    Thrombosis

heartwire    Comment    Send    Print    Share    Cite    Tweet this    Text size

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**MRI of Implantable devices: Do we need safer devices, safer scanning procedures, or both?**  
MARCH 18, 2010 | Reed Miller

**La Jolla, CA -** Just as so many clinicians are cautioning clinicians against using MRI scans of patients with implantable cardiac devices until the "true risk" of MRI scans of patients with implantable cardiac devices (pacemakers and defibrillators) is adequately studied. The MagnaSafe registry launched last spring will study about 125 of a planned 250 patients with ICDs; the primary outcome of device parameter changes.

**The MagnaSafe registry** launched last spring will study about 125 of a planned 250 patients with ICDs; the primary outcome of device parameter changes.

**Dr. Robert Russo** (Scripps Clinic, La Jolla, CA) told heartwire that the purpose of the study is to accurately assess the real risk of MRI of patients with devices, so that patients can make an informed risk/benefit decision about getting a scan.

**Dr. Christian Machado** (Providence Heart Institute, Southfield, MI), whose team is working on safe procedures for MRI scans of patients with implantable devices, is optimistic that MagnaSafe will "give clinicians important valuable information with regard to safety and device interrogation," he told heartwire. He points out that most of the previous studies on MRI-device interactions have been small. They have identified potential or "theoretical" hazards, but they do not accurately quantify the real risk of those problems. "The MagnaSafe registry would be the final push to get over the hurdle of theoretical paranoia to pragmatic reality without harming the most important variable: the patient."

**Dr. Robert Russo**  
[Source: Scripps Institute]

**Differentiating Antiplatelet Therapy in ACS**  
RELEASE DATE: 01 APR 2010  
Dr. Shatt, Cannon, Gurbel, and Storey discuss new data on antiplatelet therapies for patients with ACS.  
WATCH PREVIEW    VIEW PROGRAM NOW

**ACUTE CORONARY SYNDROMES: Coagulation Cascade and Platelet Function**  
RELEASE DATE: DEC 22, 2009  
Join Drs. Alexander, Becker, and Witz for a discussion on the coagulation cascade and its role in platelet function.  
WATCH PREVIEW    VIEW PROGRAM NOW

Ha arruolato 258 pazienti, non sono state segnalate complicazioni durante l'esame di MRI a 1,5 T

# I rischi sono reali

and no electrocardiographic data were available. Irnich *et al.*,<sup>16</sup> searched for all fatalities that occurred during MR investigation and reported by the Legal Medicine Departments in Germany. Between 1992 and 2001, six fatal cases occurred for which the German public prosecutor had ordered an autopsy. All six patients were examined in private radiology practices for orthopaedic or neurological reasons. The indication for pacemaker implantation was sick-sinus-syndrome and none was pacemaker-dependent. Unfortunately, all were without any monitoring during the scan, thus the death cause is problematic. It was determined as probably VF in three cases. In the other cases the death cause was unknown, though magnet rate was 100/min, which was according to the authors, in combination with tachycardia-bradycardia syndrome, suspected to have induced fibrillation. Worldwide, no deaths have been reported during physician-supervised MR procedures in the last decade.

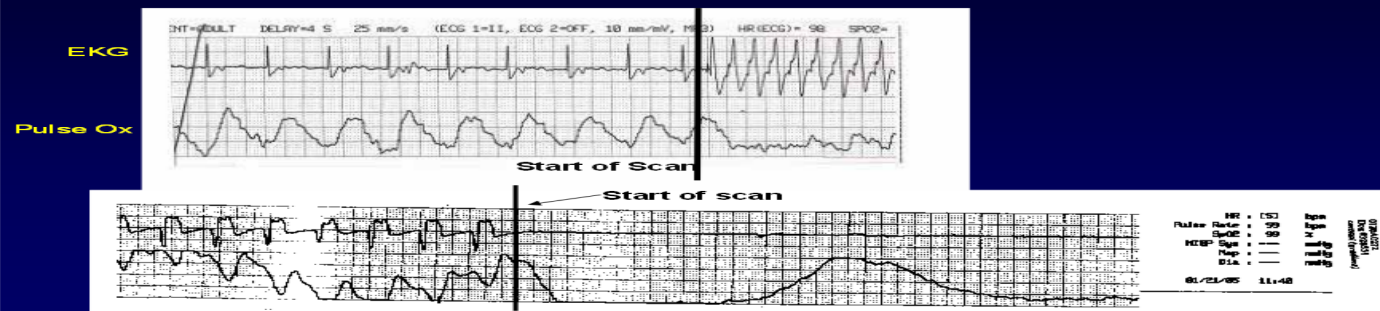
Irnich W, Irnich B, Bartsch C, Stertmann WA, Gufler H, Weiler G. Do we need pacemakers resistant to magnetic resonance imaging? *Europace* 2005;7:353-65.

## “DEATH LINKED TO HOSPITAL SCAN”

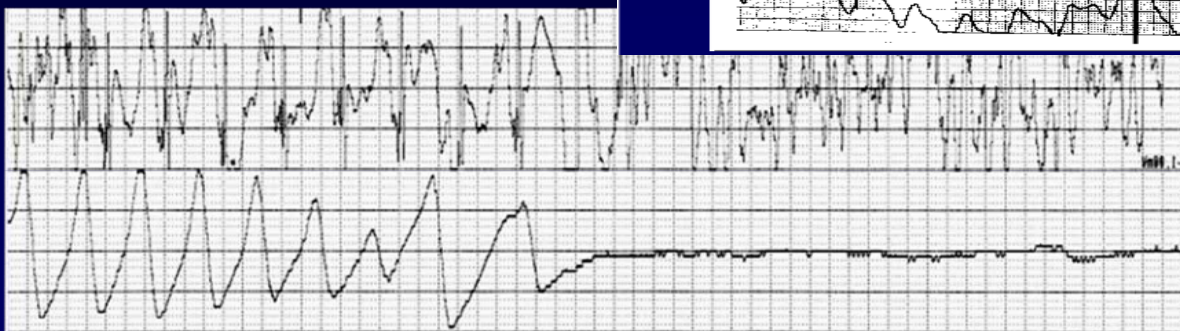
MELBOURNE, AUSTRALIA — The Alfred Hospital has announced a review of its safety procedures *after the death of a man whose pacemaker malfunctioned during a magnetic resonance imaging scan.*

*The Herald Sun*  
 Thursday April 13 2000-04-13  
 News Corporation Melbourne Australia

Stimolazione ad elevata frequenza con ipotensione e desaturazione (in alto), ASISTOLIA (in basso)



Fibrillazione ventricolare asincrona ad ele





Nel 2008 inizia l'era dei pacemaker “compatibili” con la Risonanza Magnetica

Shinbane et al. *Journal of Cardiovascular Magnetic Resonance* 2011, **13**:63  
<http://www.jcmr-online.com/content/13/1/63>



**REVIEW**

**Open Access**

## Magnetic resonance imaging in patients with cardiac pacemakers: era of “MR Conditional” designs

Jerold S Shinbane<sup>1\*</sup>, Patrick M Colletti<sup>2</sup> and Frank G Shellock<sup>2</sup>

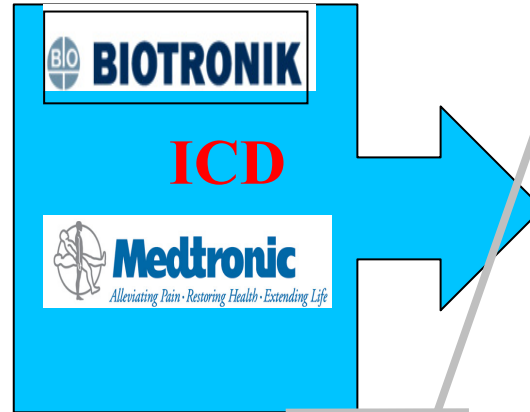
# Tecnologia MRI

## CRTD

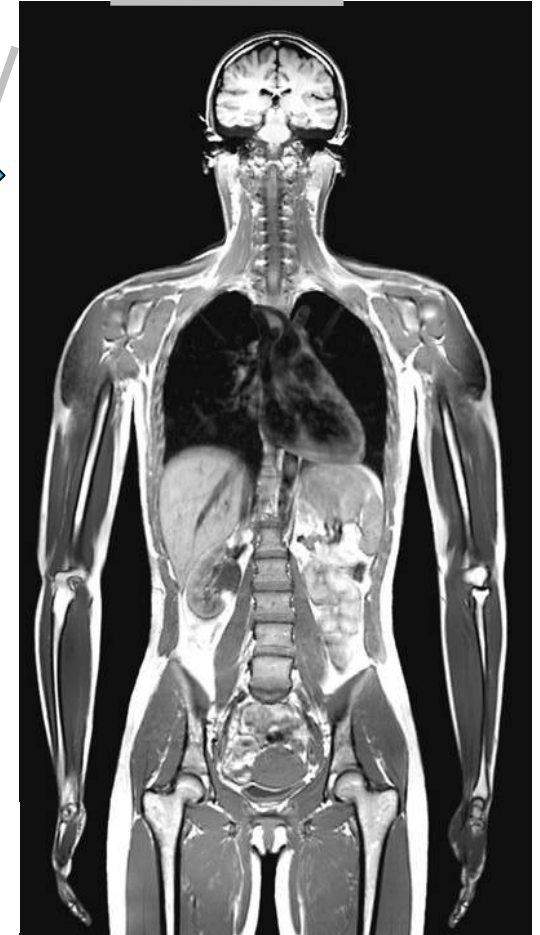
No FULL BODY



## Pacemakers



FULL  
BODY  
SCAN !



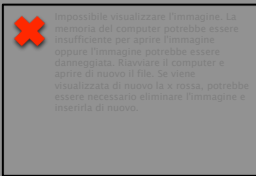
# **È tutto risolto?**

- e... la normativa ?**
- e... le linee guida ?**

# Normativa: il punto

esiste una discordanza tra normativa *Europea* e *Italiana*

- Ci sono nel mercato **device ‘convenzionali’** (non MRI-Conditional): sono *device* marcati CE per i quali il fabbricante (sia di scanner che di device) **non ha certificato** l’esecuzione di esami di RM, indicandone la controindicazione. *L’utilizzo del device in esami di RM (uso off-label) sposta la responsabilità dal fabbricante al medico.*
- Ci sono nel mercato device **MRI-conditional**, **certificati** per poter essere ragionevolmente sicuri durante l’esecuzione di esami MRI, ma con limitazioni di utilizzo specifiche indicate dai fabbricanti.



# Vige ancora .... Il decreto ministeriale 2 agosto 1991



## D.M. 2 agosto 1991

### AUTORIZZAZIONE ALLA INSTALLAZIONE ED USO DI APPARECCHIATURE DIAGNOSTICHE A RISONANZA MAGNETICA

*SUPPL. ORD. G. U. n. 194 del 20.8.1991*

Debbono essere escluse da analisi RM persone portatrici di pace-maker cardiaco; altre protesi dotate di circuiti elettronici; preparati metallici intracranici o comunque posizionati in prossimità di strutture anatomiche vitali; clips vascolari o schegge in materiale ferromagnetico.

## **Documento di consenso**

**Dispositivi cardiaci impiantabili attivi e risonanza magnetica:  
aspetti tecnologici, inquadramento normativo e modelli  
organizzativi**

**Gruppo di lavoro:** Istituto Superiore di Sanità, Associazione Italiana Fisica Medica, Federazione Italiana Cardiologi, Società Italiana Radiologia Medica, Associazione Italiana Aritmologia e Cardiostimolazione, Associazione italiana Ingegneria Clinica.

## Il problema *NON* è completamente risolto dai *device* MRI-conditional attualmente in commercio

- I pacemaker attuali sono certificati solo per scanner a 1.5 T ed alcuni fino a 3 Tesla, con eventuali ulteriori esclusioni in termini di **distretto anatomico studiabile, di intensità di gradiente, di potenza depositata sul paziente** (= tipo di sequenza MRI), **geometria del gantry** (aperto o chiuso)
- Esiste una significativa porzione di pazienti con impianti *convenzionali* (“non MRI conditional”) che potrebbero trovarsi nelle condizioni cliniche per le quali ci sarebbe un significativo beneficio diagnostico da un esame MRI.
- Esiste il problema dei lead o degli impianti abbandonati
- Vigge ancora in Italia il decreto Ministeriale del 1991

Questi casi (off-label) potrebbero rimettere la decisione finale al clinico, in termini di **rischio/beneficio** per il paziente (case-by-case).

# I ruolo delle linee guida (*device convenzionali*)

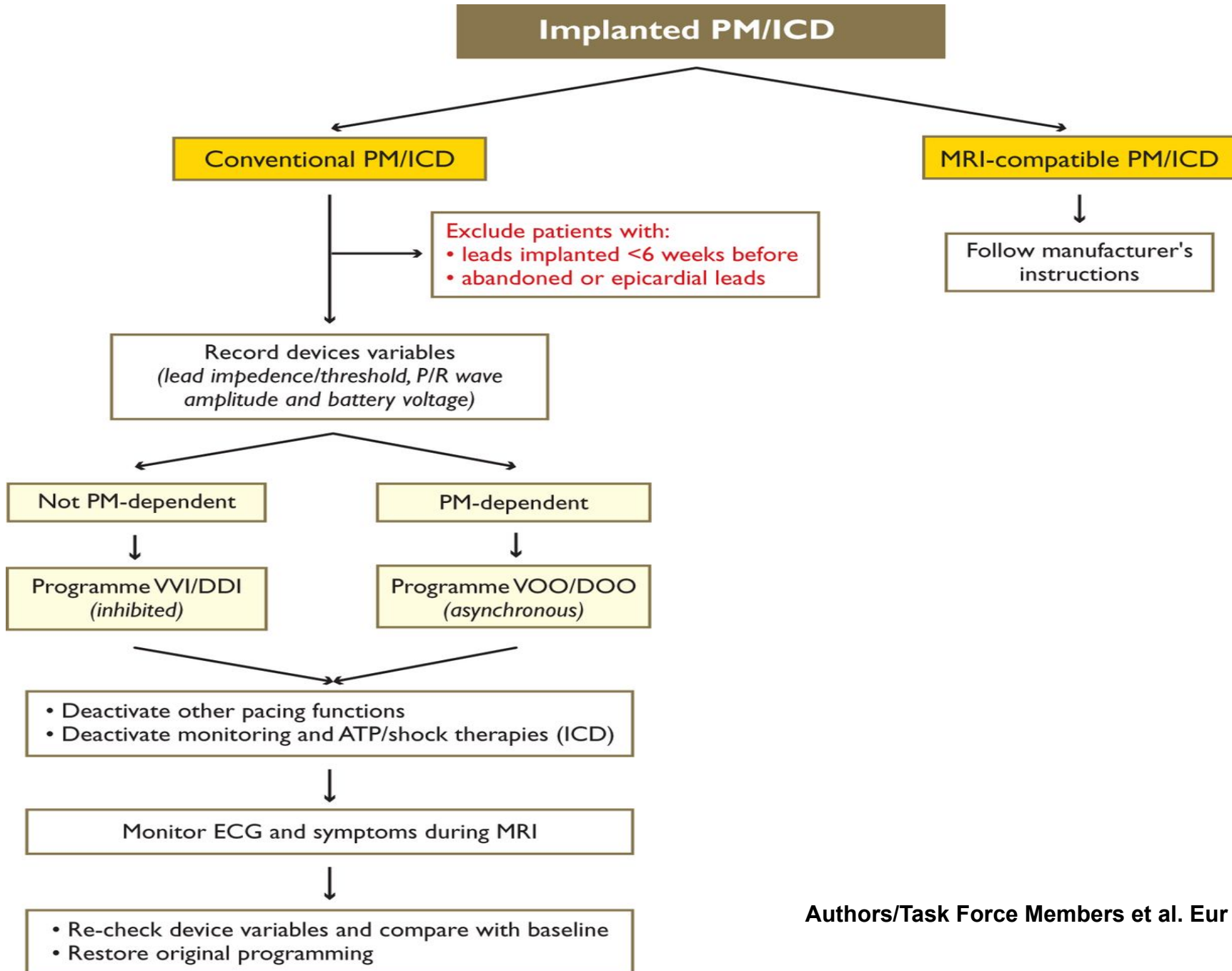
- Le linee guida delle società scientifiche **non hanno una valenza normativa**, tuttavia rappresentano lo stato dell'arte ed il *consensus* della comunità scientifica. Hanno quindi un valore nel determinare eventuali scelte/responsabilità (ad esempio nell'uso off-label)
  - *ACR Guidance Document for Safe MR Practices: 2007*
  - *AHA-ACCA (NASCI, SCMR): Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Device (2007)*
  - *ESC: Magnetic resonance imaging in individuals with cardiovascular implantable electronic device (2008)*
  - *Task Force Members et al. Eur Heart J 2013;*

...It is recommended that the presence of implanted cardiac pacemakers or implantable cardioverter defibrillators (ICDs) be considered a **relative contraindication** for MRI.

**Should an MRI be considered, it should be done on a case-by-case and site-by-site basis, and only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge....**

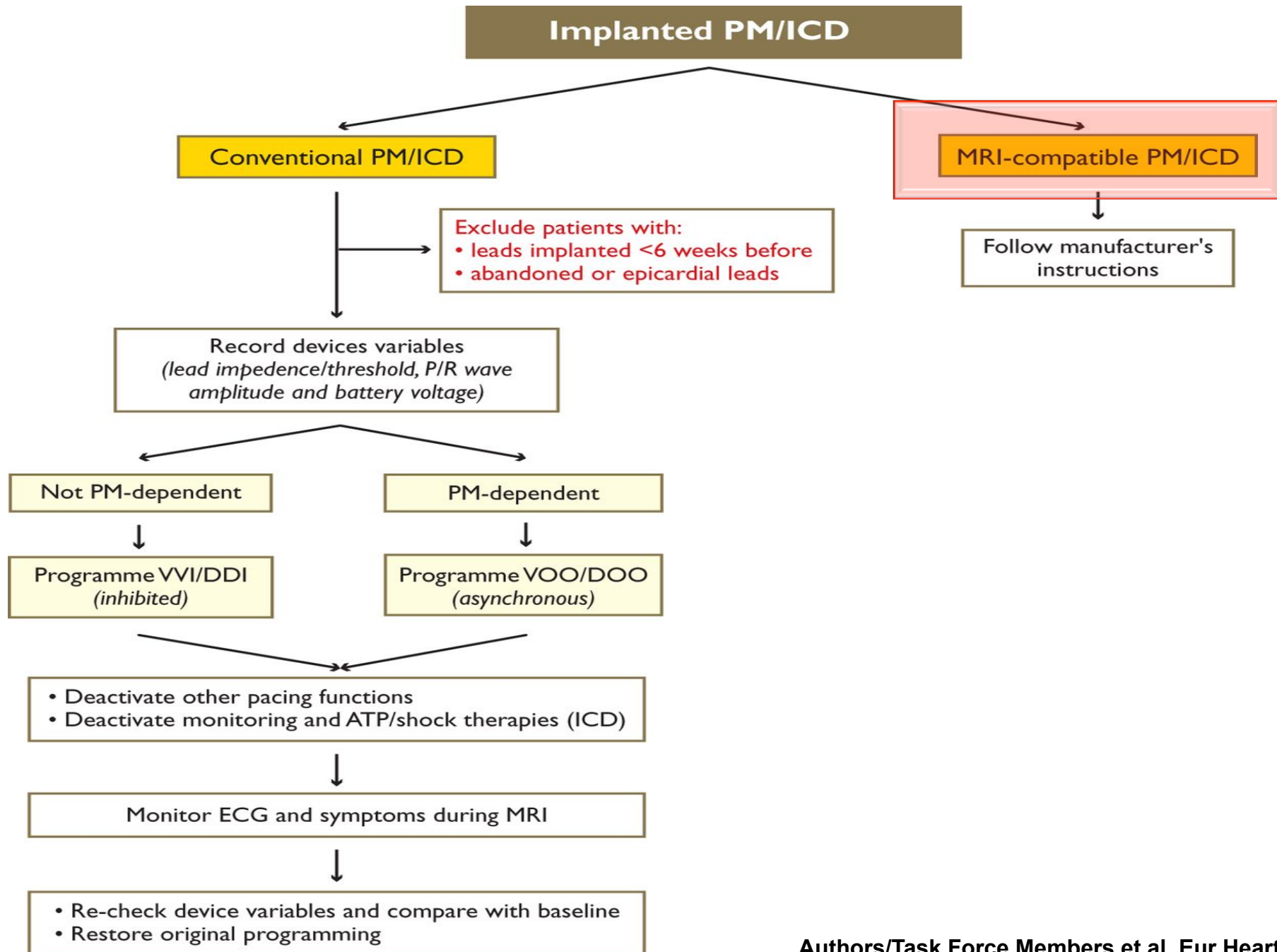


# Safety precautions for magnetic resonance imaging (MRI) in patients with conventional cardiac devices.



Authors/Task Force Members et al. Eur Heart J 2013;

# Safety precautions for magnetic resonance imaging (MRI) in patients with conventional cardiac devices.



Authors/Task Force Members et al. Eur Heart J 2013;

# Simbologia e terminologia associata al *device* relativamente ai rischi connessi con MRI



***MRI Safe:*** “il dispositivo non comporta alcun tipo di rischio in ogni possibile condizione di ambiente MRI.”

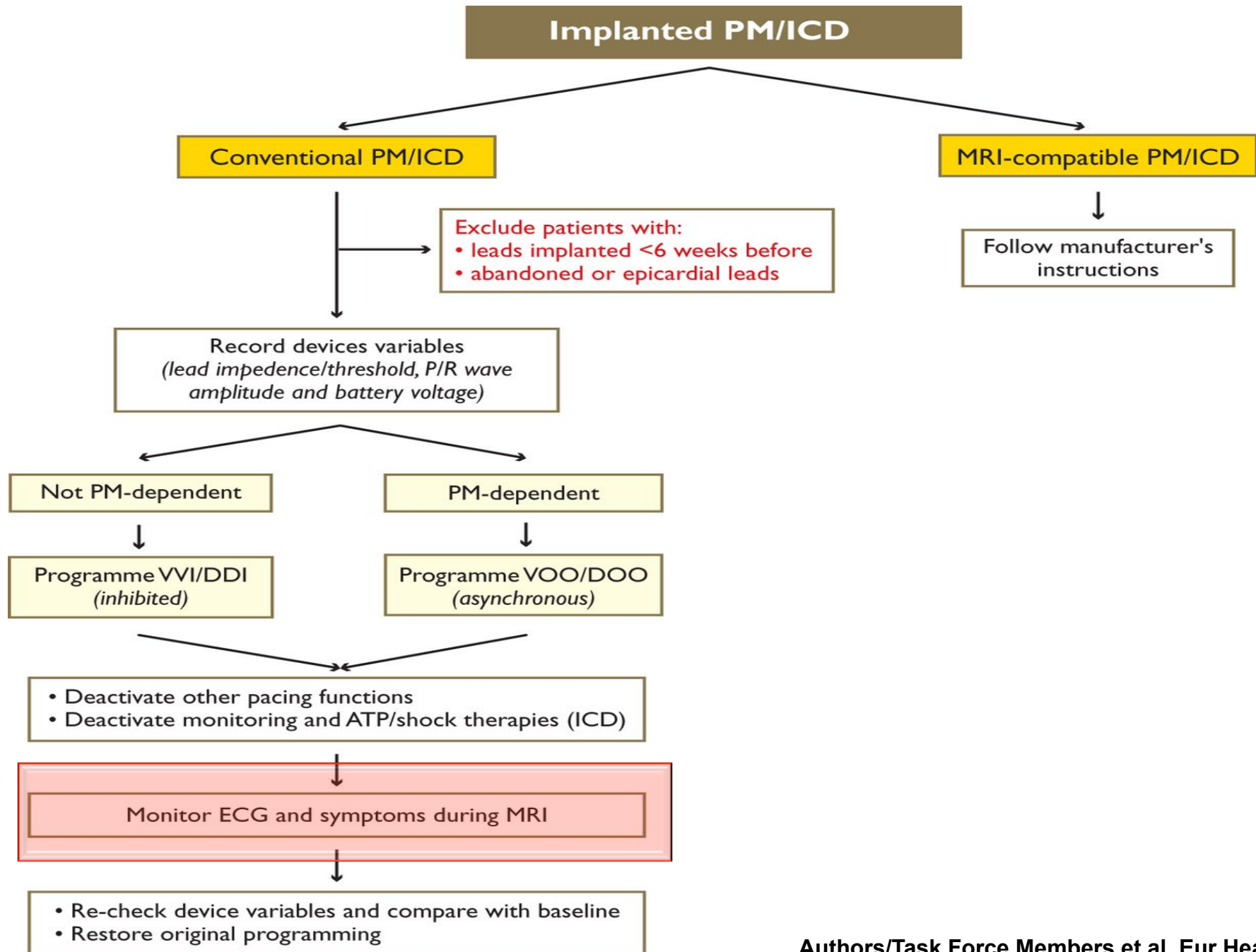


***MRI Conditional:*** “il dispositivo ha dimostrato di non porre rischi reali in un determinato ambiente MRI, sotto specifiche condizioni di utilizzo. Le condizioni di esposizione che definiscono lo specifico ambiente MRI includono l'intensità del campo magnetico, il gradiente spaziale e le variazioni temporali (dB/dt) dello stesso e l'energia depositata espressa in termini di SAR (Specific Absorption Rate). Possono inoltre essere richiesti requisiti aggiuntivi, come una particolare configurazione del dispositivo.”

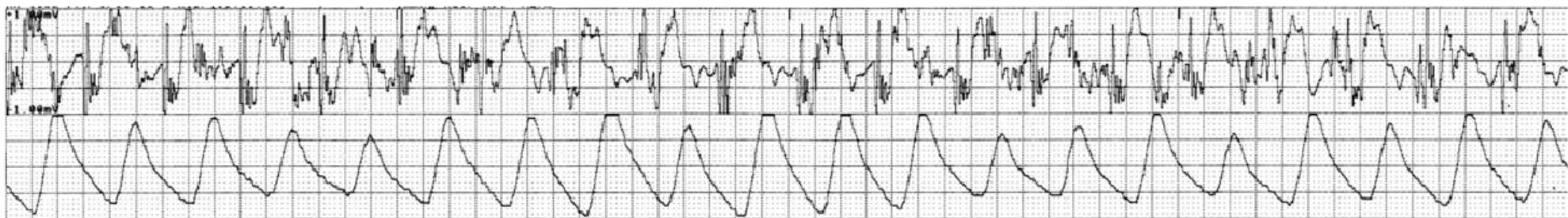


***MRI Unsafe:*** “il dispositivo comporta rischi provati in ogni tipo di ambiente MRI.”

# Safety precautions for magnetic resonance imaging (MRI) in patients with conventional cardiac devices.



Authors/Task Force Members et al. Eur Heart J 2013;



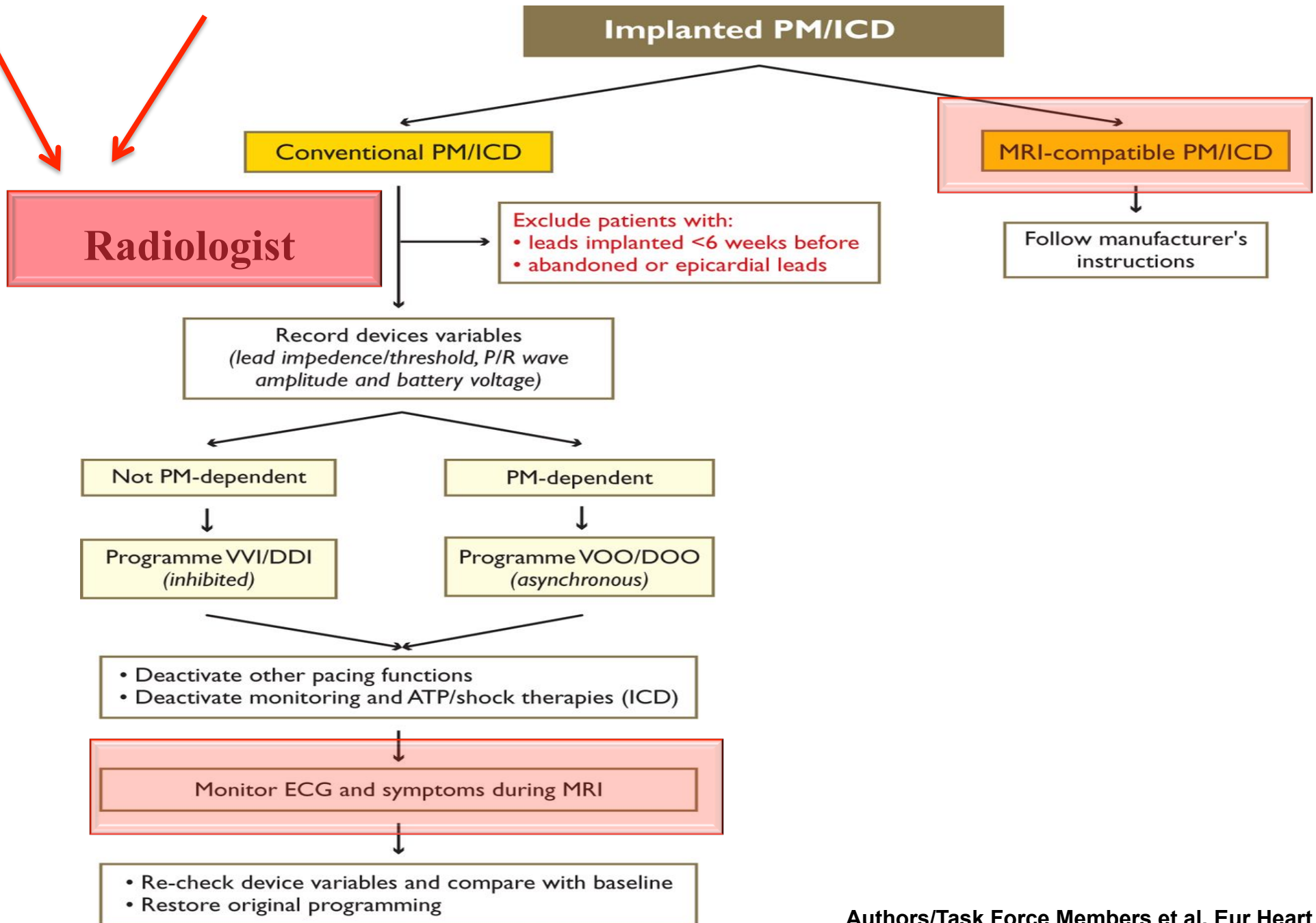
**Figure 1** Simultaneous recording of ECG (top row) and pulse oximetry (bottom row) during MRI of a PM-dependant patient. RF noise artefacts severely overlay the ECG, but leave pulse oximetry and the diagnostic value of it unaffected.

Europace 6 september 2013



Bisignani *Europace in press*

# Safety precautions for magnetic resonance imaging (MRI) in patients with conventional cardiac devices.



Authors/Task Force Members et al. Eur Heart J 2013;

# ... Come si esegue

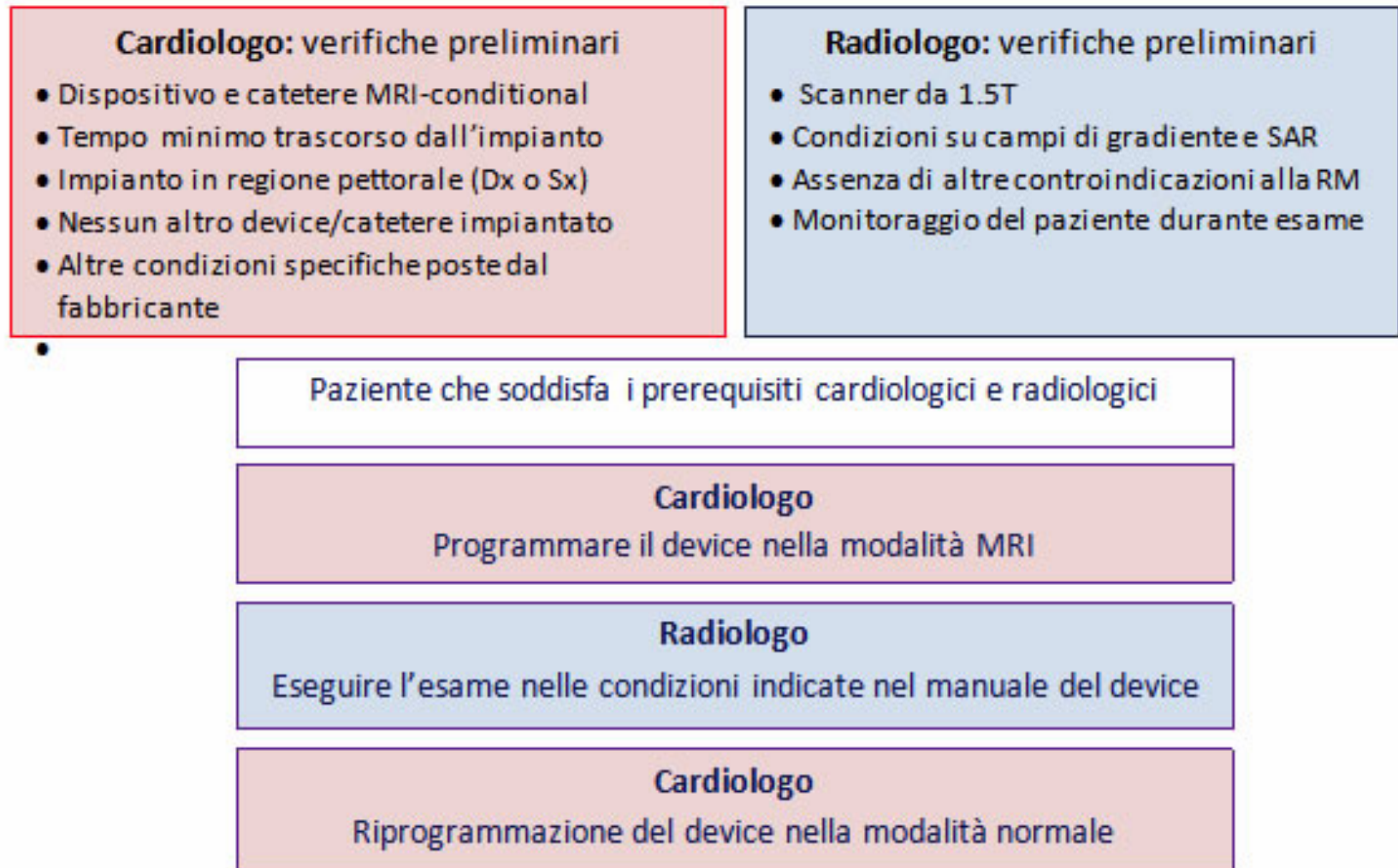


Figura 3: Esempio di flow-chart per la pianificazione di un esame MRI, in paziente con impianto MRI-conditional.

# La RM *CARDIACA* può essere eseguita nei pazienti con devices

## Editorial

### The Role of Cardiac MRI Stress Testing “Make a Better Mouse Trap . . .”

Gerald M. Pohost, MD; Robert W.W. Biederman, MD

**N**ear the turn of the 20th century, Ralph Waldo Emerson said, “If a man can make a better mouse trap than his neighbor, the world will make a beaten path to his door.” In the 1990s, we have seen particularly illuminating examples of this prediction: from the model T

corresponding wall motion abnormalities in territories supplied by critically stenosed coronary arteries. To date, three imaging technologies have been coupled with “stress”: (1) radionuclide imaging with  $^{201}\text{Tl}$ ,  $^{99\text{m}}\text{Tc}$  sestamibi, or similar agents to allow detection of perfusion defects and

**“We are now on the brink of a revolution...the future of MRI is no longer over the horizon...it is certain that MRI will be the cornerstone of cardiovascular imaging in the next millennium.”**

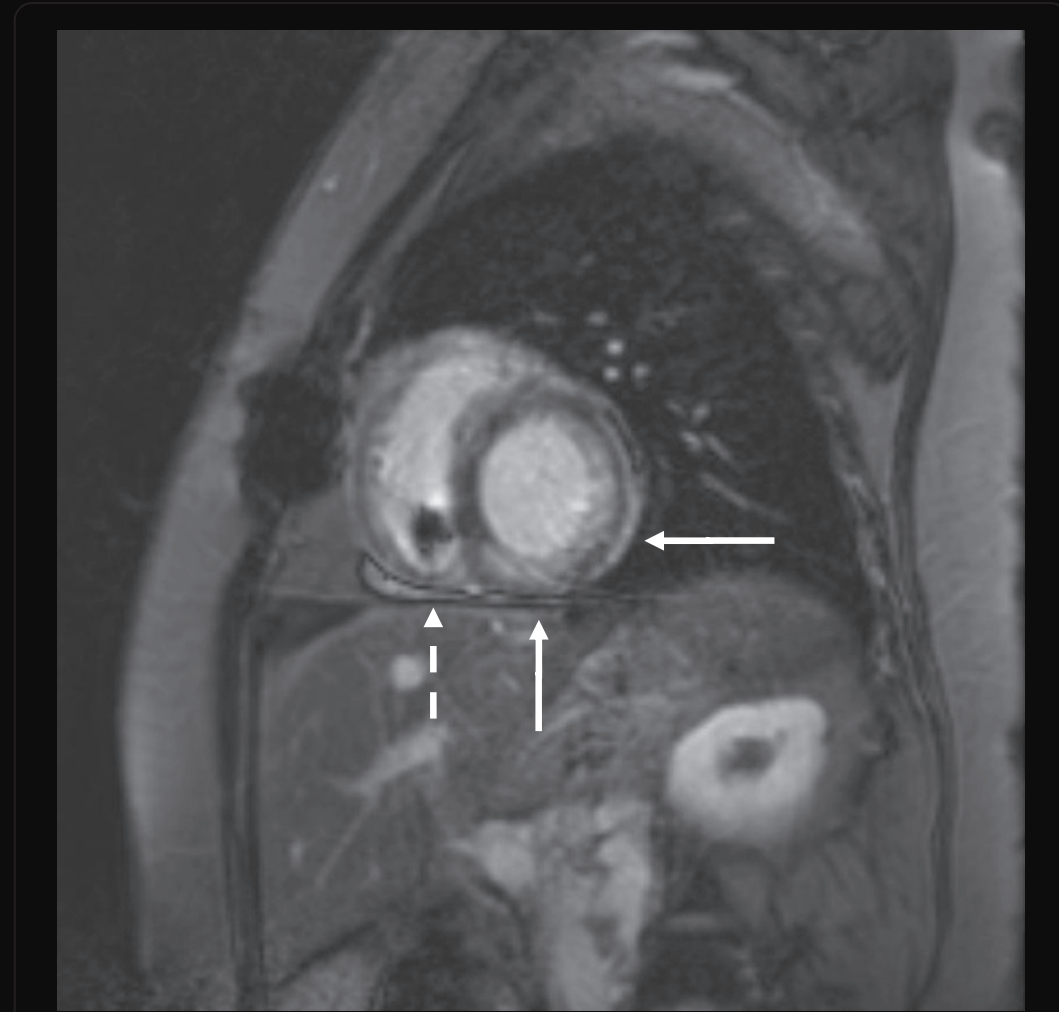
See p 1697

We are now on the brink of another revolution, reaffirming Emerson’s adage. Cardiac imaging has seen little to parallel its rapid advancement. In a short time, we have moved from x-ray methods for imaging coronary artery calcification in the 1950s by simple fluoroscopy, to the selective coronary arteriogram of Mason Sones in 1958, to the translation of

important is related to several factors. In large part, it is related to the fact that 2D stress echocardiography, although important and widely used, has several interrelated limitations. These include the requirement for an echocardiographic “window” and the effect that an inadequate window has on the ability to evaluate wall motion, substantial dependence on the skill of the sonographer, and the physical limitations inherent in ultrasound.



# RM CARDIACA



European Heart Journal Advance Access published March 21, 2015



European Heart Journal  
doi:10.1093/eurheartj/ehv086

**REVIEW**

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*Clinical update*

# **Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: how far have we come?**

## CONCLUSIONI

- *RM conditional* significa che la RM è sicura **SOLO** in specifiche condizioni che possono variare da ditta a ditta.
- Non usare dispositivi RM conditional quando disponibili rappresenta l'esclusione di una metodica diagnostica (la RM) dal futuro di un paziente, con dubbi sulla costituzionalità di tale scelta
- Vigge ancora la legge (D.M. 2 agosto 1991). (*documento Istituto Sup. Sanità*)
- Se necessaria RM in paz con device NON RM CONDITIONAL condividere rischi col pz , con la consapevolezza della necessità di un rischio (*sostanzialmente piccolo secondo alcuni*) che va affrontato eliminando così rischi più grandi (*estrazione, deficit di informazioni diagnostiche fondamentali*).
- Implica comunque **un'assunzione di responsabilità** da parte degli operatori sanitari

# Not All Pacemakers Are Created Equal: MRI Conditional Pacemaker and Lead Technology

1062 Journal of Cardiovascular Electrophysiology Vol. 24, No. 9, September 2013

## ACR Guidance Document on MR Safe Practices: 2013

*...The effects of MRI scanning in paced patients with nonconditional system appear to be unpredictable...*

*...each MR conditional device is unique, there are no “universal” labeling guidelines that are applicable for all*

**...However, research over the last decade led to the recommendations in the 2013 ESC guidelines, where MRI might be possible if following certain prerequisites.**

**è finito il tabù...**

