



A Physiologists Perspective: How Home Monitoring has Contributed to Patient Management and Clinical Outcomes

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Pacemaker Diagnostics

- Pacemakers can help answer key clinical questions regarding device status, clinical status and arrhythmia status of the patient.
- Pacemakers can give useful insight into disease progression and long-term patient management questions.

Evolution of pacemaker diagnostics

15yrs ago

Rate Response Histogram



Today!

HRV, Fluid monitoring, AF, Ve's....etc etc!

Pacemaker Diagnostics

- Modern day pacemakers have advanced diagnostics which can be a useful tool in diagnosing and monitoring disease progression
- Pacemaker diagnostics will inevitably increase in both number and sophistication
- The challenge for the device companies is to ensure that diagnostic data can be easily interpreted

Follow-up Care After Implantation

- Appropriate follow-up care for the patient and device is critical for achieving maximal clinical benefit and for preventing and managing significant events
- Advanced Devices store diagnostic information which forms the basis for improving patient management and patient outcomes – a lack of continuous monitoring of the device **may result in suboptimal patient care**

Follow-up care needed for the device:

- To document appropriate functioning and correct abnormal behavior
- To identify device end-of-battery life and organize replacement in advance

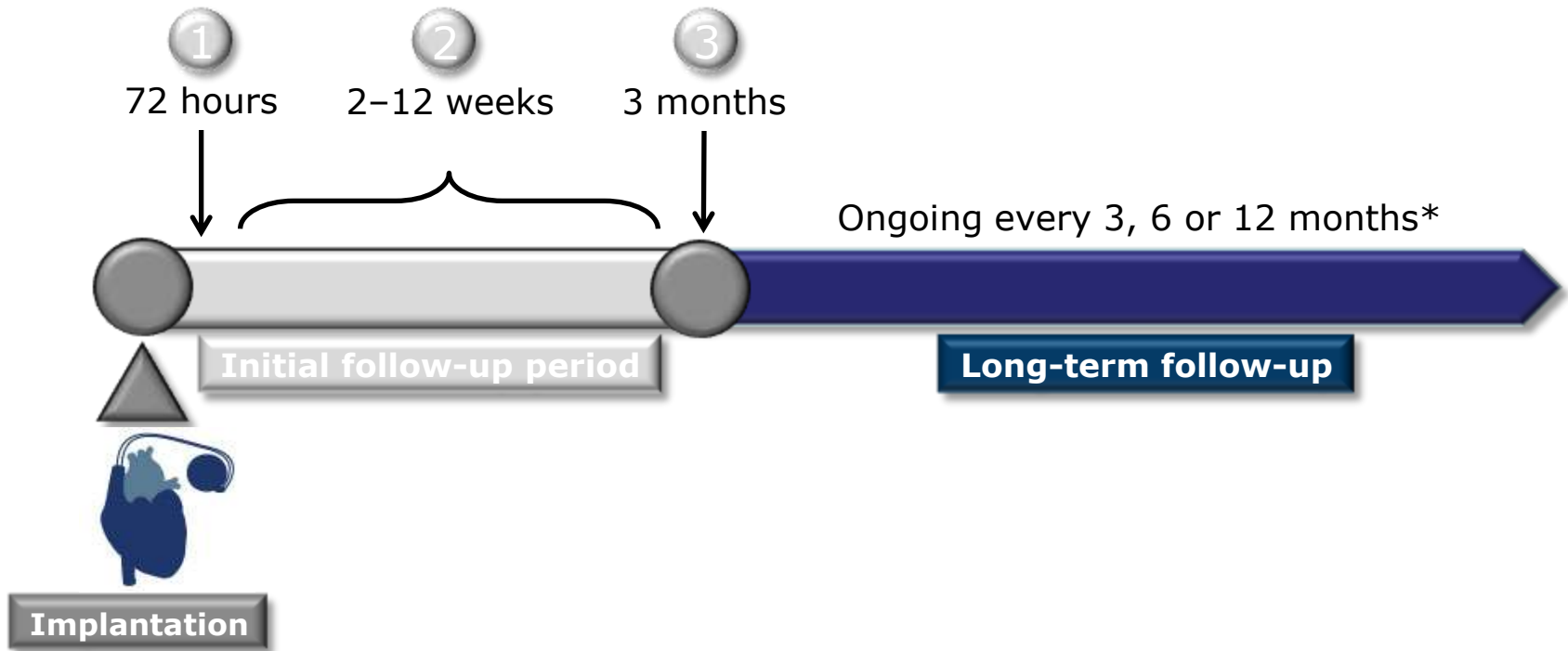
Follow-up care needed for the disease:

- To document the nature and frequency of symptoms and appropriateness of device response
- To detect symptomatic and asymptomatic events
- To monitor response to therapy



Current Guidelines and Practice

- Scheduled in-office follow-up visits are recommended to maximize the functionality of devices, and to optimize patient management and safety**



*Follow-up frequency is dependent upon device and patient need



Development of device follow up

Calendar-based in-office follow-up visits could be supplemented and/or replaced by:

Calendar-based
remote monitoring
+
No continuous
monitoring

Calendar-based
remote monitoring
+
Continuous
monitoring

Need-based
remote monitoring
+
Continuous
monitoring

What are the challenges of changing the model of follow up compared to the traditional calendar-based in-office follow-up

?

Create a Template

New patient

Administration

Users

New user

Patient groups

New patient group

Transmitters

Option templates

Site Tools

Home

What's new

User profile

Contact

Imprint

Help

Sign Out

Status

Device settings

Recordings

History

Patient profile

Options

Save/print (PDF)

Device

+ + Off

ERI

Programmer triggered message received

Lead

+ + Off

RA pacing impedance: or

RA lead check

RA sensing amplitude (daily mean):

RA pacing threshold:

RA capture control disabled

RV pacing impedance: or

RV lead check

RV sensing amplitude (daily mean):

RV pacing threshold:

RV capture control disabled

Bradycardia/CRT

+ + Off

Ventricular pacing (Vp):

Atr. and ven. arrhythmia

+ + Off

Number of atrial arrhythmia episodes per day:

Template




HF monitor				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	CRT pacing: < 85%
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Mean ven. heart rate: > 80 ppm
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Mean ven. heart rate at rest: > 80 ppm
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Mean VES/h: > 50 VES/h
Episode				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ven. monitoring episode with long duration: > 5 min
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ven. therapy episode with long duration: > 2 min
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ven. episode with acceleration of atri. rhythm below: 500 ms
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ven. episode with acceleration of ven. rhythm
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ven. episode with fulfilled ATP time-out criterion
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ven. episode with 2 or more started shocks
<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Episode details received
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Periodic IEGM received
Home Monitoring				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	First message received
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	No messages received for: 21 days
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Patient not viewed for: 3 months
Finding options comment				
<input type="text"/>				
<input checked="" type="checkbox"/> Apply <input type="checkbox"/> Reset <input checked="" type="checkbox"/> Cancel				
Template functions				
Load	<input type="text" value="Default settings"/>	<input type="checkbox"/>		

Rhythm Alert Template

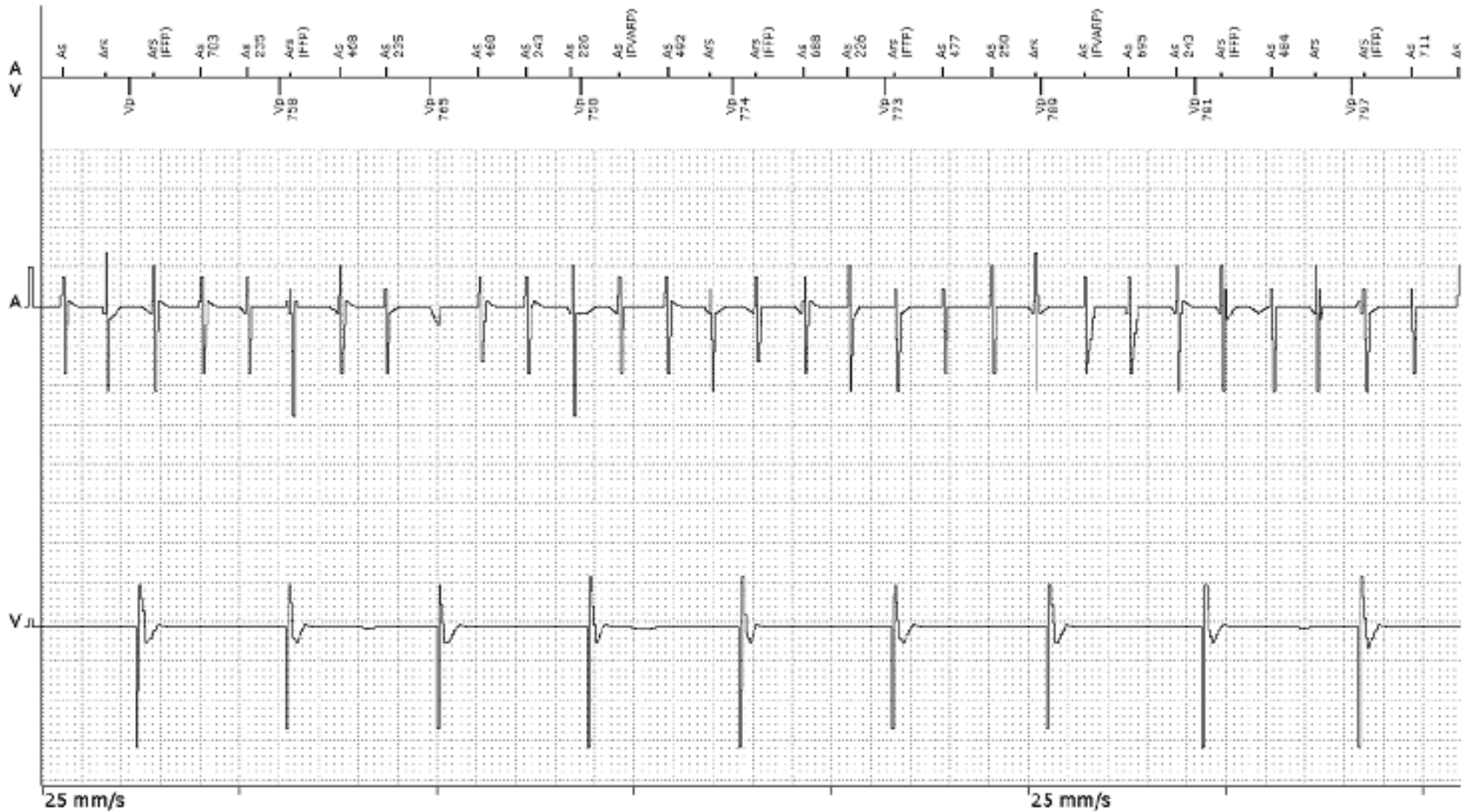
Atr. and ven. arrhythmia				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Number of atrial arrhythmia episodes per day: <input type="text" value="> 10"/>
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Atrial burden: <input type="text" value="> 25%"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Number of mode switching per day: <input type="text" value="> 50"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Duration of mode switching per day: <input type="text" value="> 75% of day"/>
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Long atrial episode / mode switching episode detected (ongoing at time of transmission)
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Mean ventricular rate during mode switching <input type="text" value="> 130 ppm"/> or <input type="text" value="> 10% of day"/>
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Number of high ven. rate (HVR) episodes per day: <input type="text" value="at least one"/>
HF monitor				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Mean ven. heart rate: <input type="text" value="> 80 ppm"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Number of PVC per hour: <input type="text" value="> 50 PVC/h"/>
IEGM				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Periodic IEGM received
Home Monitoring				
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Off
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	First message received
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	No messages received for <input type="text" value="21 days"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Patient not viewed for <input type="text" value="3 months"/>
Finding options comment				
<input type="text"/>				

Monitoring of AF burden and Rate Control

Summary of arrhythmia alerts

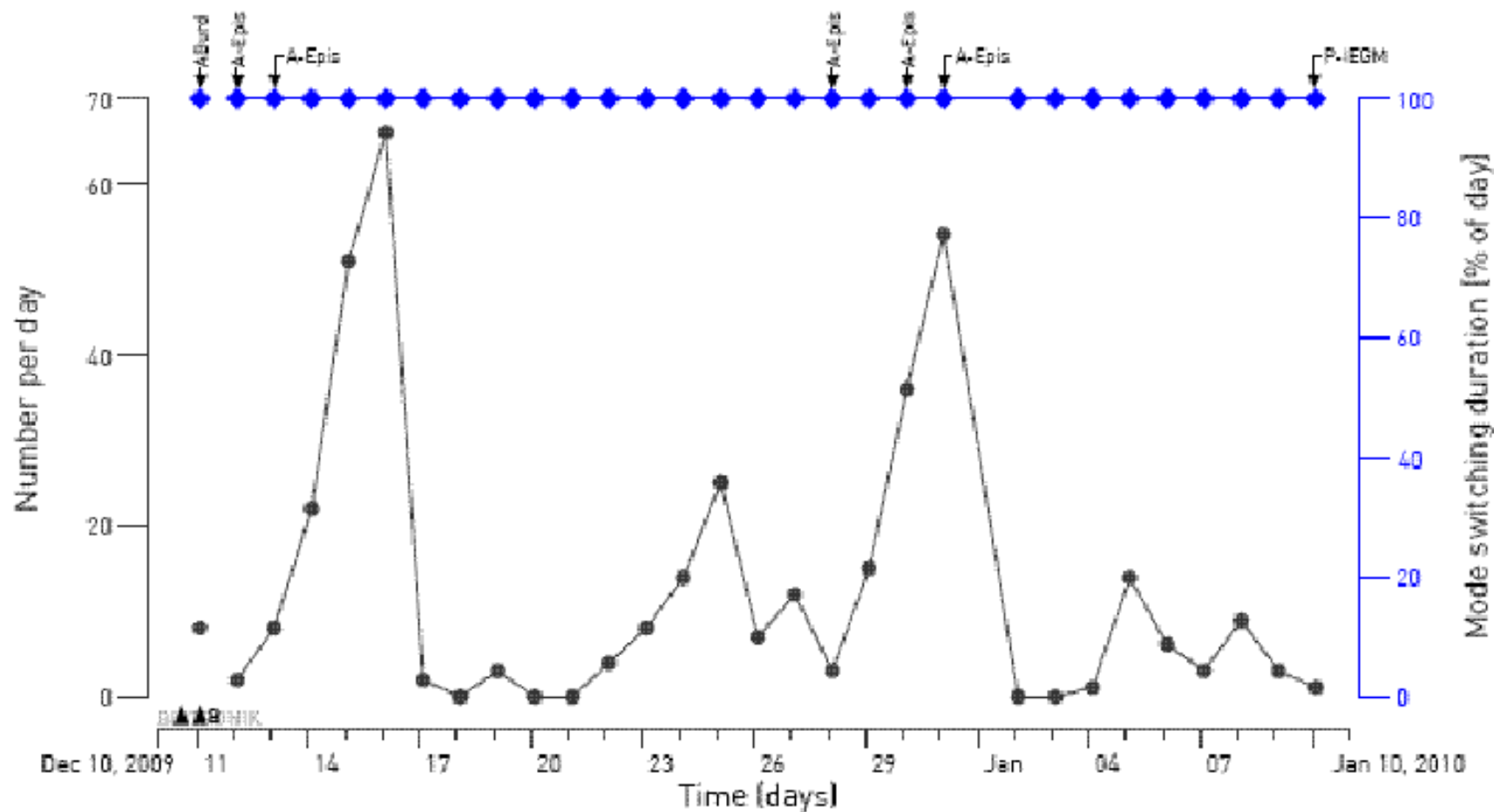
Status on Feb 17, 2010 1:54 AM		Evia DR-T / SN: Implantation: Feb 11, 2010
Status		Save/print (PDF)
Device settings		
Holter		
History		
Patient profile		
Options		
Summary		
Device		
Lead		
Bradycardia/CRT		
Atr. arrhythmia		
Ven. arrhythmia		
Physiologic. param.		
HF monitor		
	Atr. arrhythmia Atrial burden above limit (> 25%) Last value 48% measured on Feb 17, 2010 1:49:00 AM	New.
	Ven. arrhythmia Number of high ven. rate episodes (HVR) above limit (at least one) Last value 1 episode(s) measured on Feb 17, 2010 1:49:00 AM	New.
	Administrative First message received on Feb 17, 2010 1:51:38 AM Please compare the status with the data of the last follow-up	New.

Is it better to see this <24hrs, 3+ months or 12 months?



Mode switching

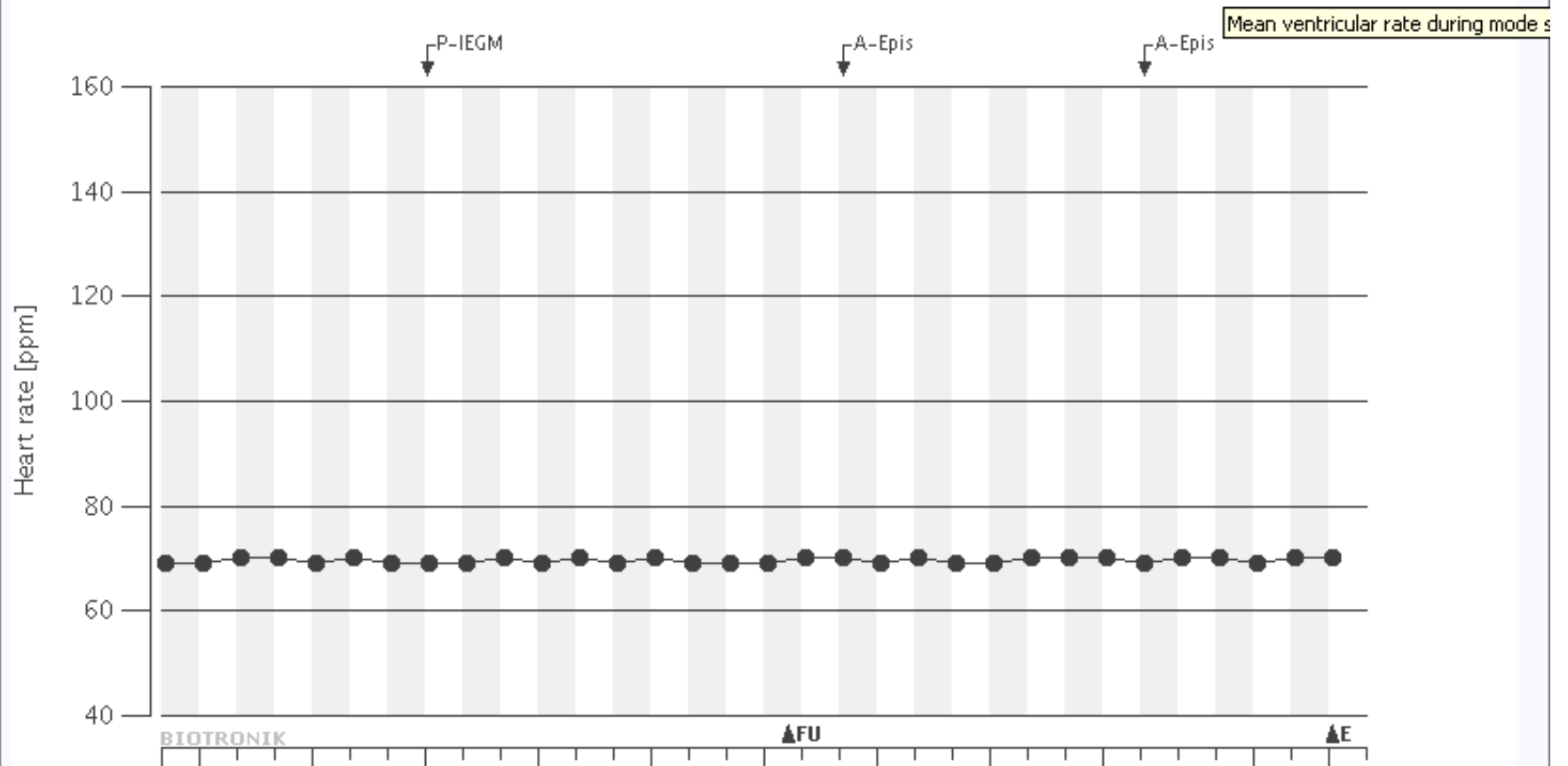
- Number of mode switching per day
- ◆ Duration of mode switching [% of day]



Mean ventricular rate during mode switching

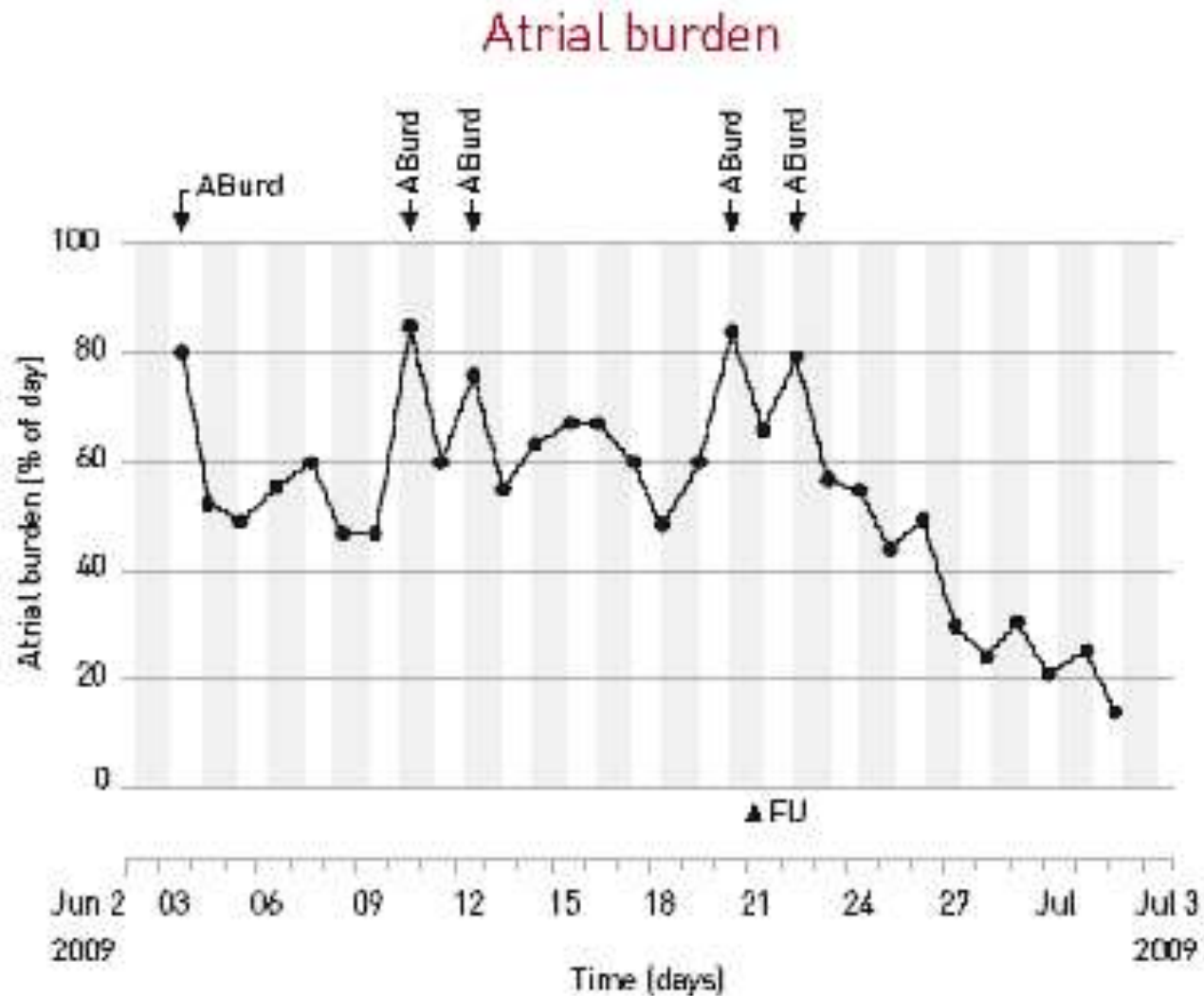
Mean ventricular rate during mode switching

● Mean ventricular rate during mode switching [ppm]



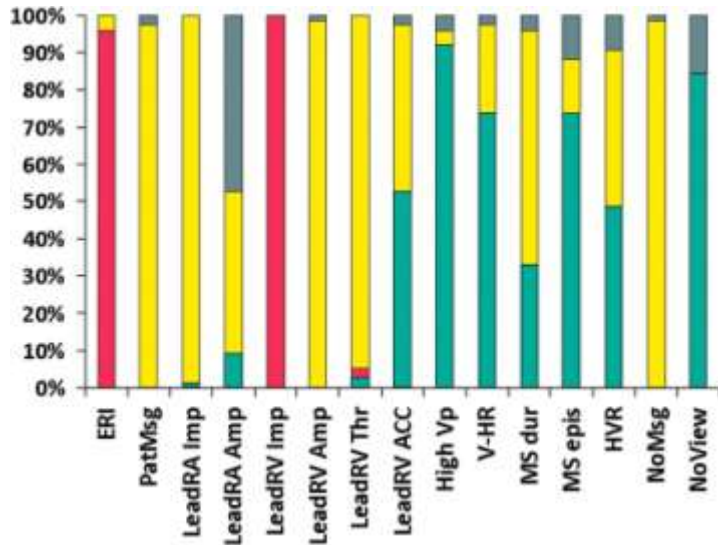
Monitoring of AF burden and Rate Control

Detailed diagnostics shows any increase or decrease in AF burden

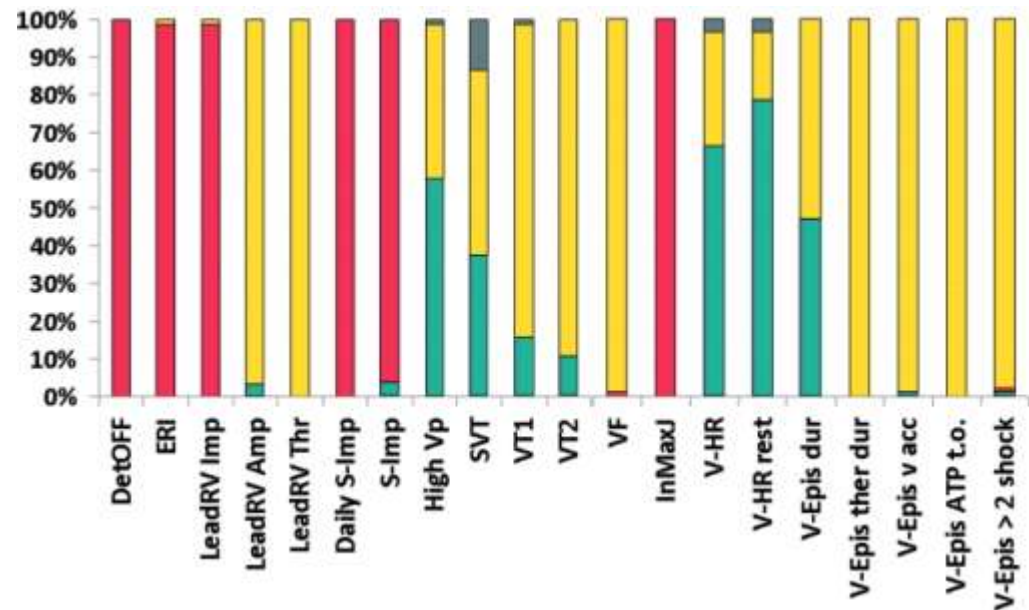


Monitoring for all?

- Historically more attention is paid to critical technical data than to patients' clinical profiles, probably to limit an excessive flow of data into the centre.
- Accurate alert settings, personalized to the patients' features, are essential for easier and more effective management of patients who are followed remotely.



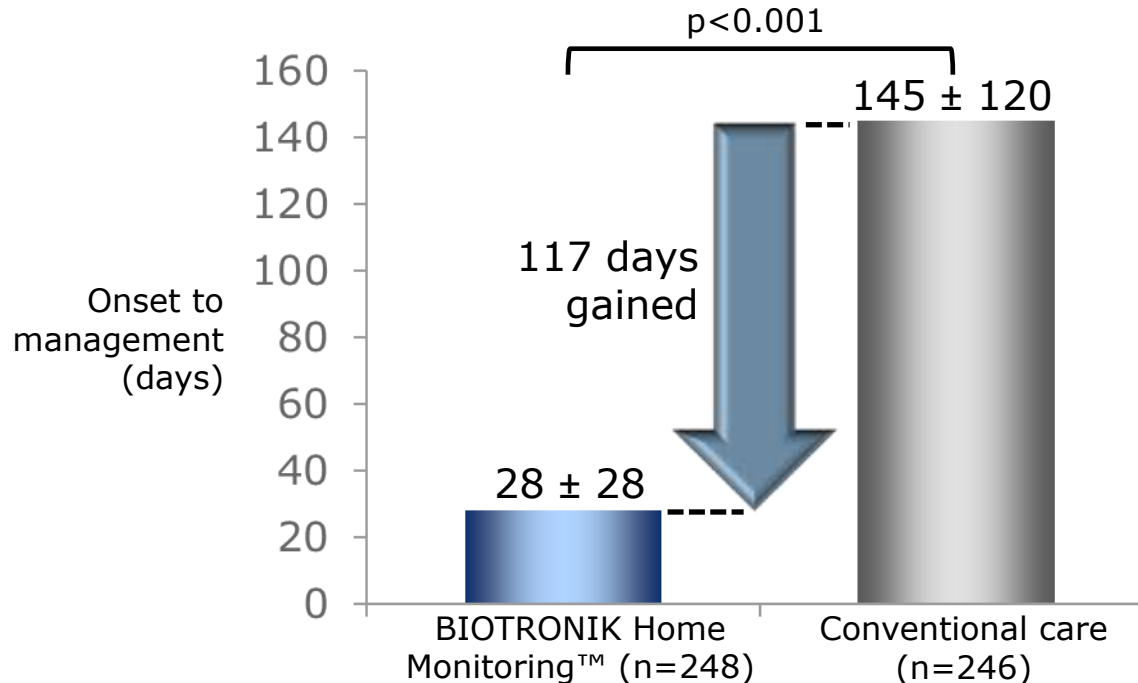
Typical Pacemaker Alerts



Typical ICD Alerts

Early Detection of Events COMPAS

Time from onset to cardiac event management in patients with PMs



Data taken from COMPAS RCT for patients with PMs¹

- The ability of BIOTRONIK Home Monitoring™ to detect cardiac events earlier than conventional care is supported by observational studies of PM and ICD populations, where events were detected up to 154 days earlier^{2, 3}**

RCT=randomised controlled trial; PM=pacemaker; ICD=implantable cardioverter defibrillator

¹Mabo P. *Cardiostim* 2010;Jun 16–19 2010; ²Lazarus A. *Pacing Clin Electrophysiol* 2007;30(Suppl 1):S2–S12; ³Ricci RP *et al.* *Europace* 2009;11(1):54–61



Common Feedback from Physiologists

- Majority of centres focused on the critical technical data, particularly concerning lead integrity, battery depletion, and wave sensing. In contrast, less attention was paid to the clinical data such as AF and HF diagnostics
- Device clinics are often too busy....15 mins (or less!) may not be enough to focus on all the diagnostics available



Patient Management

The main potential advantage of remote control application in atrial fibrillation management is represented by **early detection** and **early reaction** to the arrhythmia occurrence.

The current device diagnostics are very sophisticated and may give the physiologist/ physician full information about arrhythmia episodes: number and duration, date and time of occurrence, onset mechanism, arrhythmia burden and heart rate during the arrhythmia.

Unfortunately, this information is available only during in-hospital follow-up, usually scheduled every 6 or 12 months, significantly delaying the reaction to atrial fibrillation. This represents a great limitation, mainly for symptomatic patients and for those with mild symptoms.



Genuine Questions Remain Today

- Remote monitoring: a cost or an investment?
- Potential increase in workload related to alert messages needs to be offset by improved patient outcome.
- It is still not clear as to whether remote device and patient management should be proposed to all patients or only to a subset that is most likely to benefit from this technology.
- Patients at increased risk of developing adverse clinical events that may benefit from early detection (e.g. atrial fibrillation, heart failure, lead dysfunction, etc.).
- What is the future of the traditional pacing clinic?



My Conclusions as a Physiologist

- Home Monitoring is an investment – Allows you to better manage the inevitable increase in device follow up
- Accurate settings of the alerts, tailored to each patient, although requiring more time be spent in the first period of remote monitoring activation, are necessary for simpler and more effective management of incoming data.
- To perform a simple and reliable analysis of the information that arrives at the hospital, the correct settings and proper administration of alert messages must be implemented. Many parameters can be adjusted and tailored to the clinical characteristics of the patient, allowing prompt notification of relevant clinical events and technical issues.



Thank You

Questions?

