

# Identifying and managing device and lead issues – Remote follow up an essential tool

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# Introduction

- Overview of Swindon Remote Monitoring service
- Case study 1
  - MHRA alert device failure
- Case study 2
  - Lead failure
- Case study 3
  - Detection loss of capture via PIEGM



# Remote Monitoring Service

- Remote monitoring offered to all patients
  - Since 2011
- RM service runs 6 days per week
  - Not Saturdays
- >2000 current patients actively followed up
- >18,000 device follow ups
  - 2011-mid 2016



# Remote FU of CIEDS

- Loop Recorders
  - No formal clinic FU
  - Ad hoc remote alerts
- Pacemakers
  - 12/12 Remote FU
    - Automatic Threshold Functions ON
- CRTP/D and ICD
  - 12/12 in clinic
  - 4/12 and 8/12 remotely (if stable)

# Staffing RM Service

- Core team of 6 physiologists
- All hold current post-graduate qualification in devices
  - BHRS
  - IBHRE
  - EHRA
- Flexible working patterns/Work from home
  - Retention
  - Recruitment



# Device Issues- Case Study 1

- 75yo Gentleman
- SJM Unify Quadra CRTD
  - January 2012
  - Secondary prevention
  - No therapies since implant



# Clinic FU 28/6/16

- Pre/Post op check
- AF with 71% BIVP
  - Previously detected via HM
- No therapies
- 100% AMS
  
- DDDR 70-120
  - Discussion regarding AVNA



# Clinic FU 28/6/16

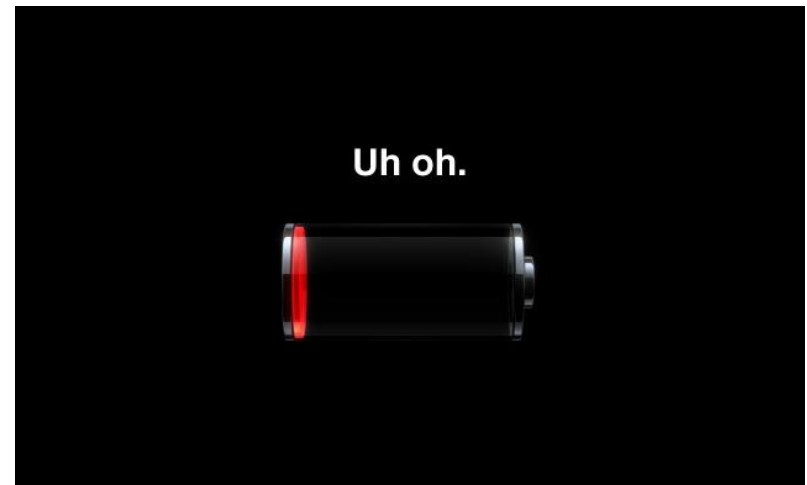
- Battery
  - 2yrs
  - 9.9 sec charge time
- A Lead
  - 2.0mV (AF)
  - 310 $\Omega$
- RV Lead
  - 1V @ 0.5ms
  - 12mV
  - 380 $\Omega$
- LV Lead
  - 1.375V @ 1.0ms
  - 850 $\Omega$
- Booked 4/12 Virtual FU





# Remote Monitoring Alert 26/9/16

- Device ERI on 24/9/16
  - No therapies
  - 90% BiVP
  - Lead values as before
- D/W manufacturers
- Admitted to CCU
  - Listed for urgent box change
- Box Change 28/9/16



# Cause of the issue

- On October 10th, 2016, St Jude Medical issued a global advisory on certain ICD and CRT-D devices manufactured before May 23, 2015.
- Advisory based on the potential for premature battery depletion associated with short circuits induced by lithium deposits.



ST. JUDE MEDICAL

10 October, 2016

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## **Important Medical Device Advisory**

### **Premature Battery Depletion with Implantable Cardioverter Defibrillator**

**Affected International Models can be found in the  
Appendix to this letter**

We are advising you of a risk of premature battery depletion associated with St. Jude Medical ICD and CRT-D devices manufactured before May 23, 2015. Affected models include Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™.

Among 398,740 devices sold worldwide, 841 devices returned for analysis due to premature battery depletion have had

# The importance of Remote Monitoring

- **PATIENT MANAGEMENT RECOMMENDATIONS INCLUDE:**
- Routine follow-up as per standard practice.
- Prophylactic device replacement is not recommended.
- **Physicians are advised to enroll impacted patients in Merlin.net™ PCN during routine follow-up visit.**
- Ensure that the vibratory patient notifier is programmed “ON” for ERI alerts and remind and demonstrate to patients how it feels when the alert is triggered during routine follow-up visit.

# Impact of Advisory

- 24 affected patients
- 23 already remotely monitored (96%)
- 1 non RM patient
  - Previously refused
  - Registered once advisory was explained
- 1 patient who was prophylactically box changed as device was for reposition
- No further events from this subset of devices

# Interesting Points

- Patient did not respond to vibratory alert
- Had not yet had AVNA
- What would have happened .....
  - Had AVNA
  - Not registered on HM



# Lead Issues- Case Study 2

- MRS Pacemaker
  - 51 years old
  - Dizzy Spells, SSS Brady, Wenckebach
  - DR PPM
  - Implanted 26/11/14
  - Active RV/RA leads
  - 77 minutes case time
  - “Multiple RV positions” “Small R waves”
- Placed on Remote Monitoring pre-discharge

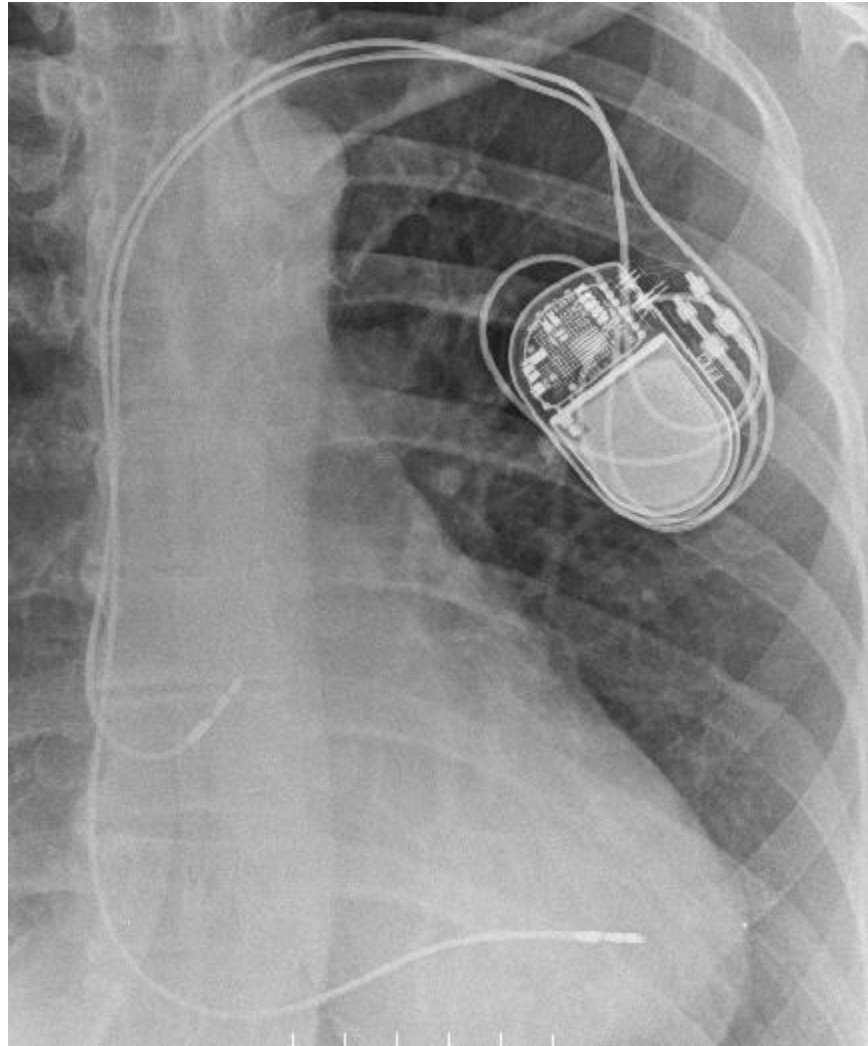
# Case Study 2- Measurements

- Implant
  - Threshold
    - 0.5V @ 0.5ms
  - Impedance
    - 772 $\Omega$
  - R wave
    - 12.8mV
- Post Implant 26/11/14- Same day discharge
  - Threshold
    - 0.6V @ 0.4ms
  - Impedance
    - 565 $\Omega$
  - R wave
    - 11.6mV





# Post Implant X-Ray

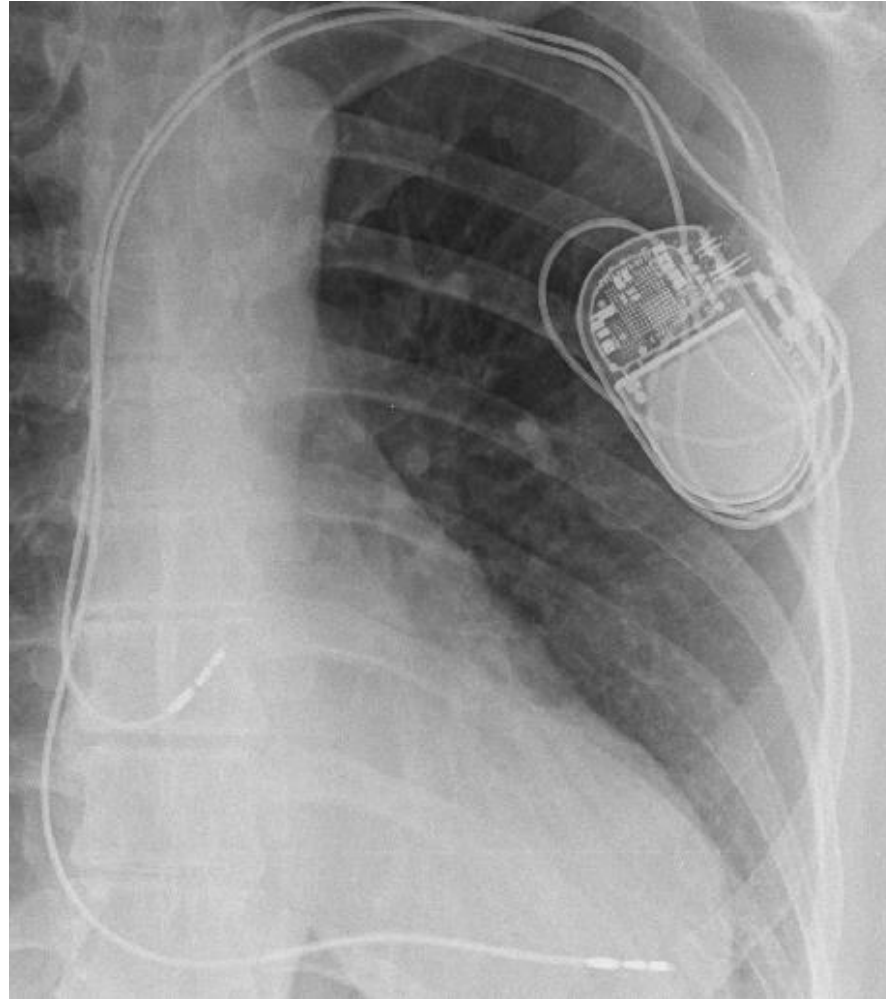


# 1 day post implant

- Attended A+E
- Chest Pain
- X ray performed
- Discharged sent home with painkillers and advice
- No PPM check requested
- Cardiology advice not sought
- ECG reported as normal



# A+E X-Ray



# Meanwhile

- The morning of attendance at ED
- Red alert via Remote monitoring
  - RV LEAD FAILURE
- This was Saturday
  - No action until the following Monday am

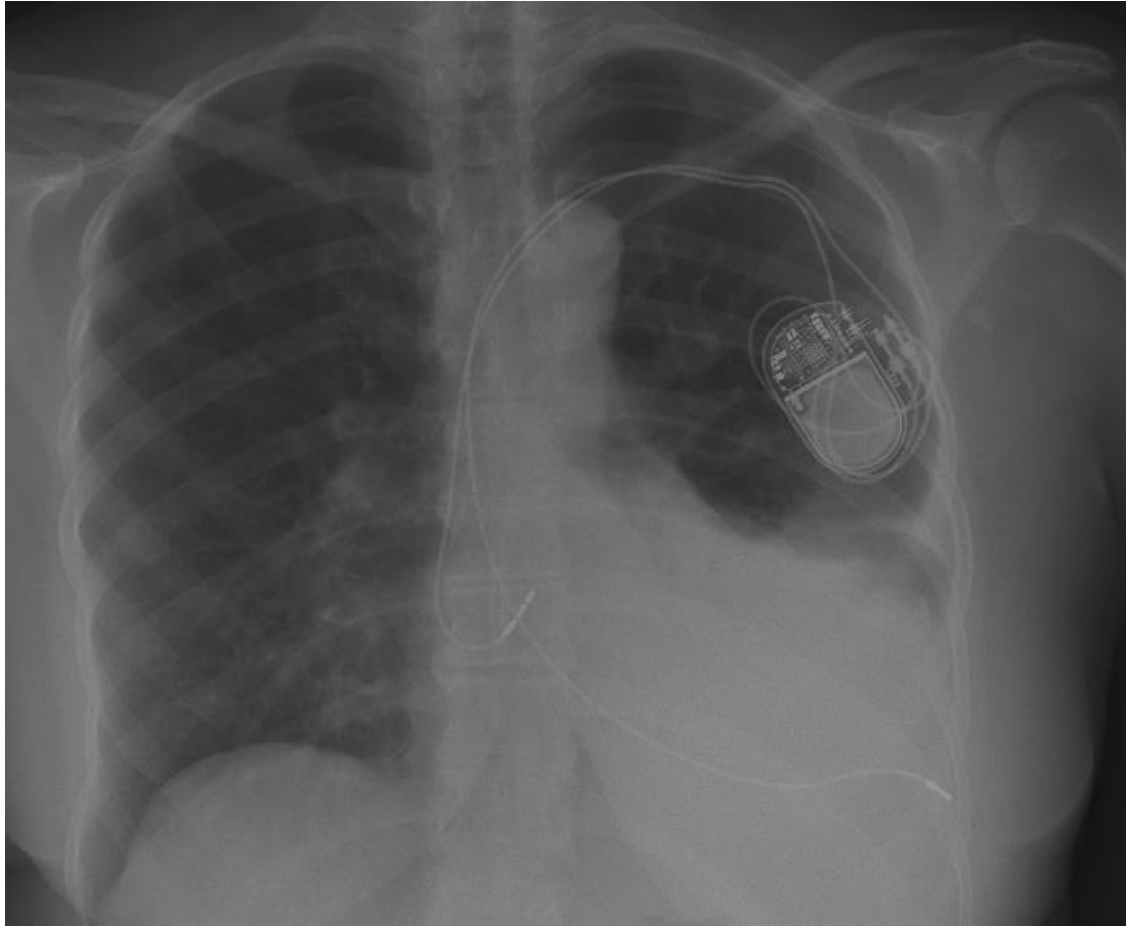


# Action

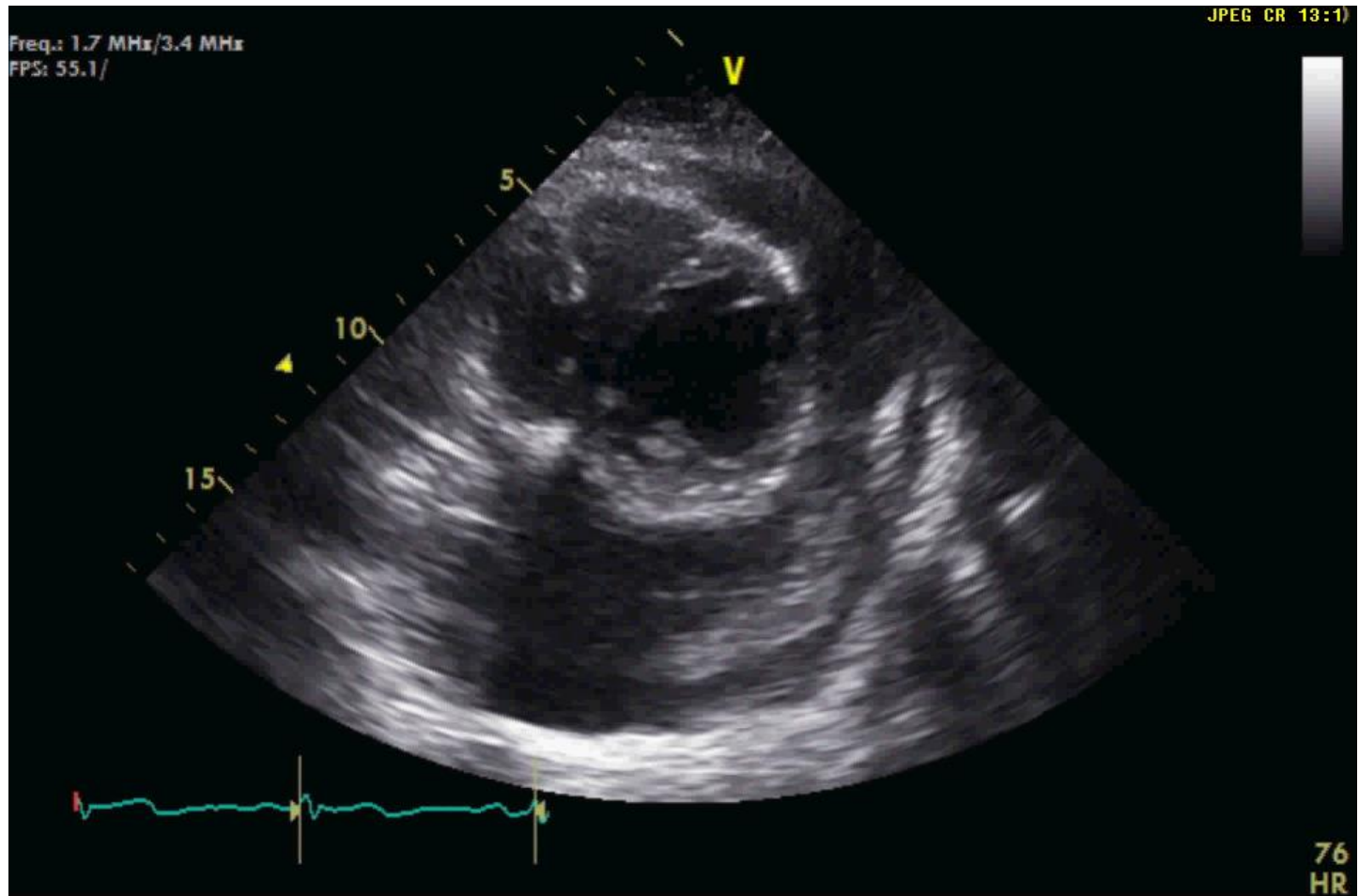
- Brought in to clinic Monday PM
  - Measurements
    - Threshold
      - No capture 7V @ 1.5ms (uni/bi)
    - Impedance
      - 290 $\Omega$
    - R wave
      - 2mV
- X Ray
- Echo
- CT Scan



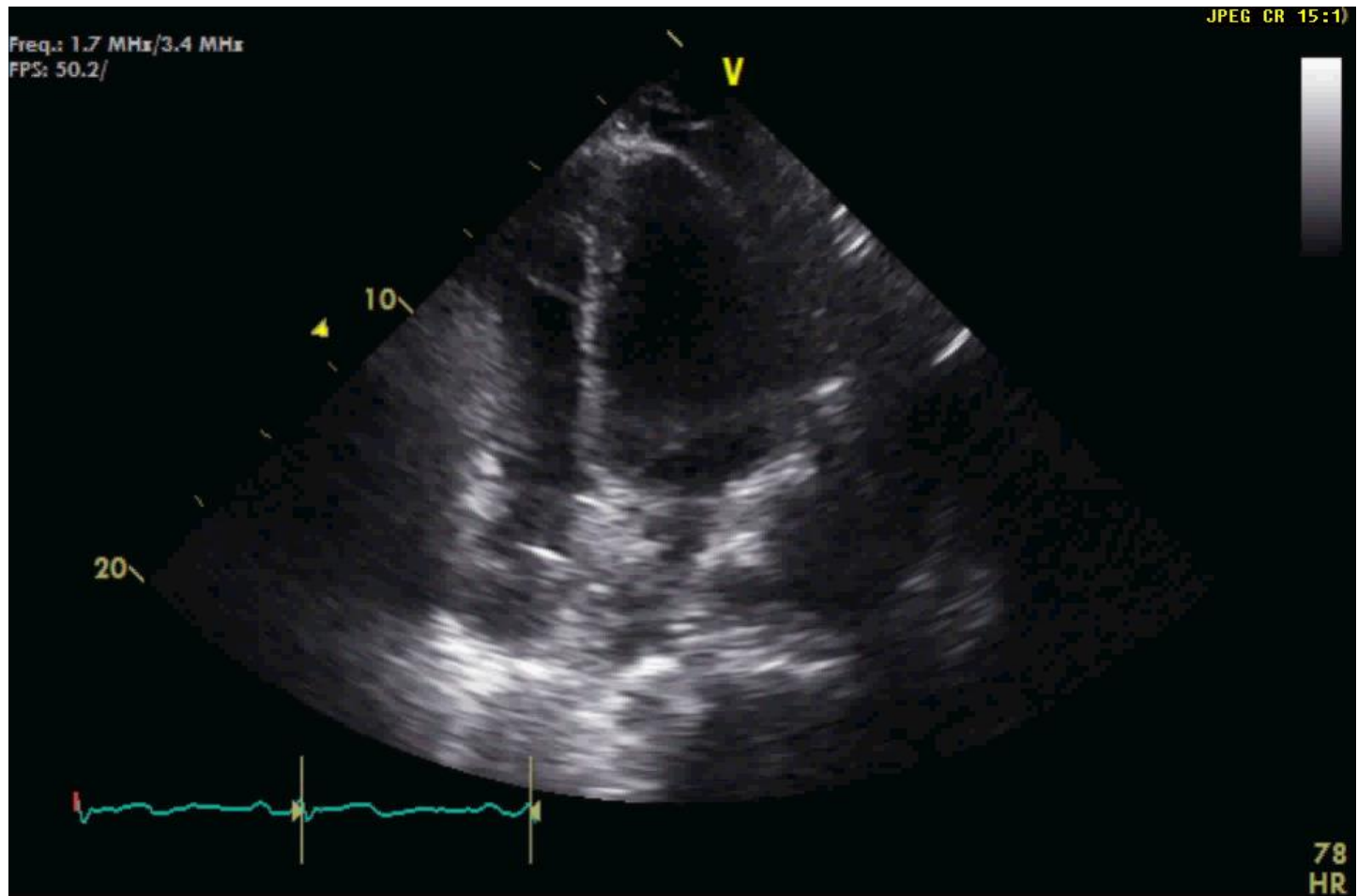
# Clinic X-Ray



# Echo

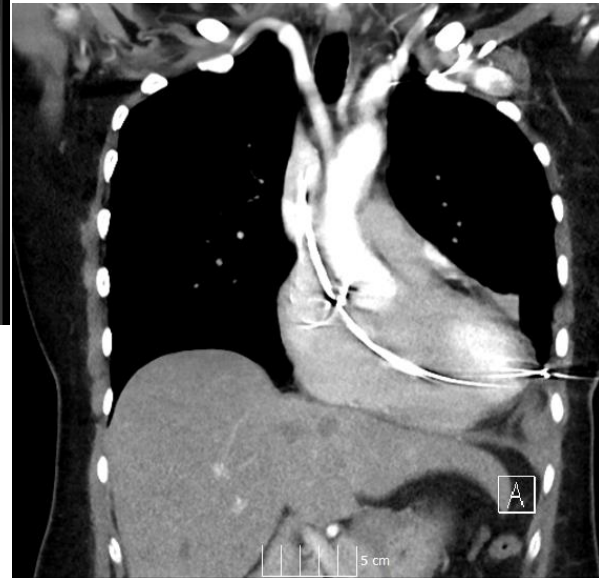
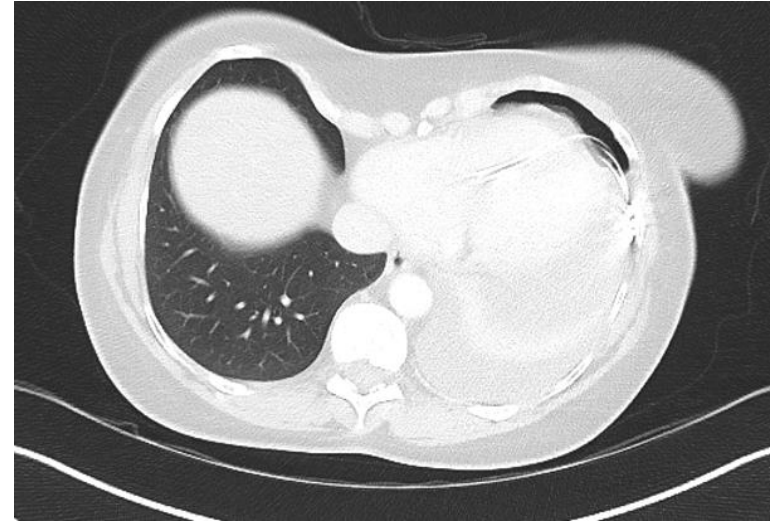


# Echo





# CT Scan



# Conclusion

- Admitted to CCU
- Referred to tertiary centre for surgical lead removal
- Learning points
  - 24hrs+ until red alert acted upon
    - ?need for weekend cover
  - Need for cardiology review in ED



# RM Issues-Case Study 3

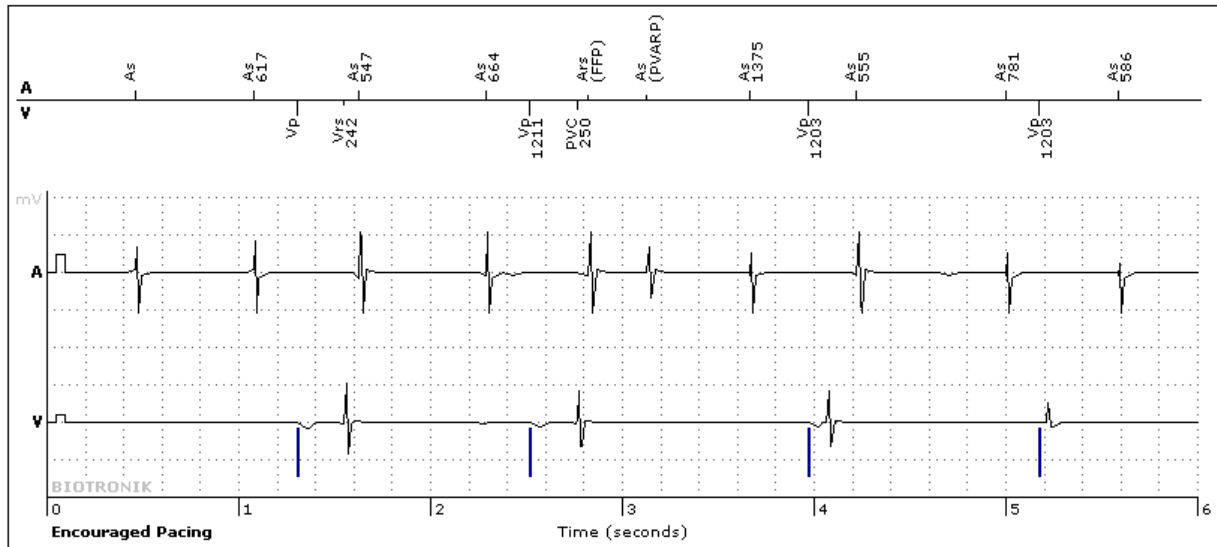
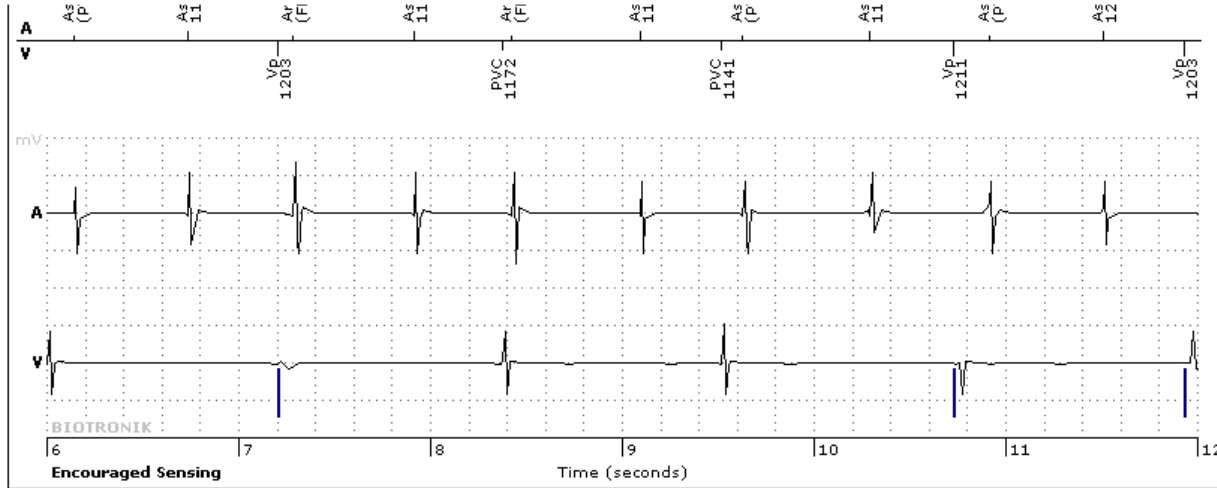
- 94yo gentleman
  - 2:1 AV Block
  - Mildly impaired LV function
  - Severe AS
  - Previous CABG
  - Multiple non cardiac co-morbidities
  - Biotronik Epyra 8 DR-T 12/12/2016
    - DDI 50 (tracking Sinus Tachy)
    - Capture management would not work
    - Registered on HM



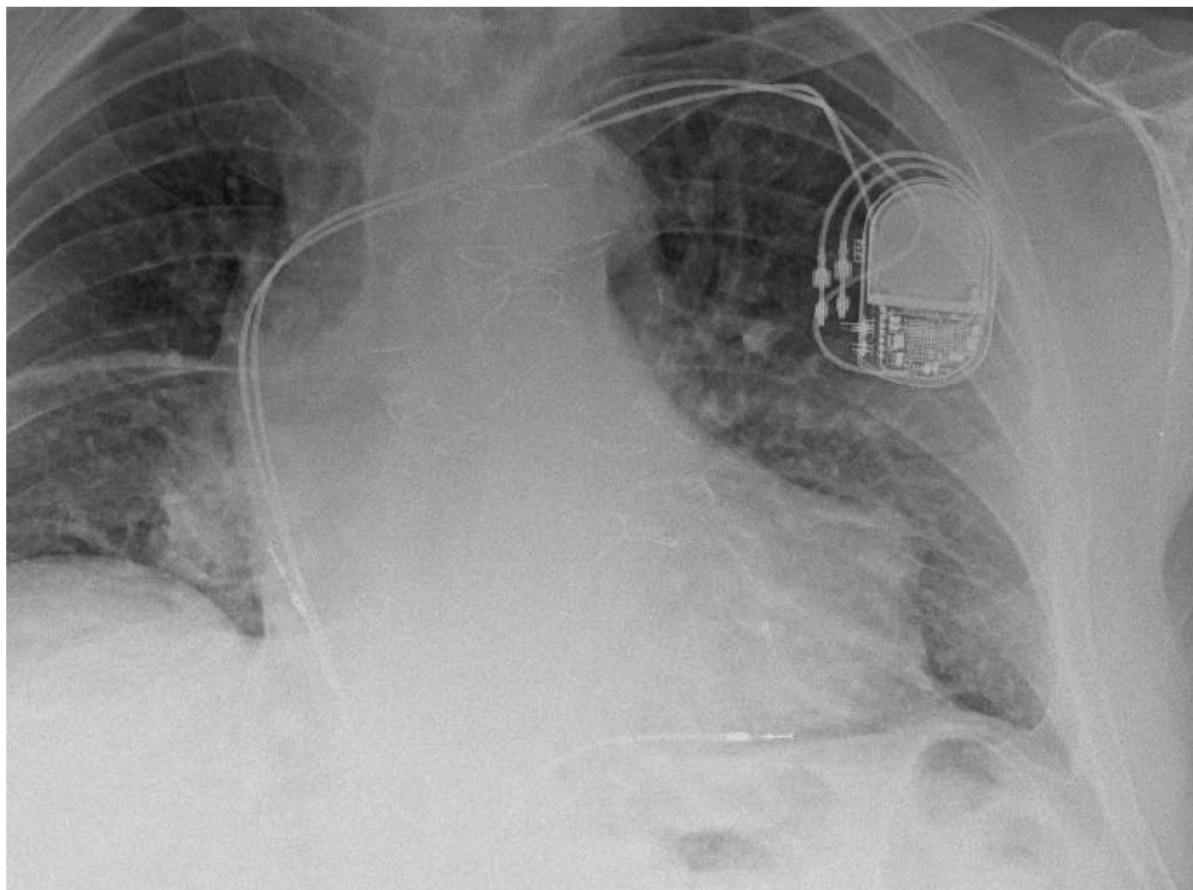
# PIEGM Sent 11/1/17

- Failed to attend 4 week post implant check
  - Check of 30 day PIEGM
- Device reported no anomalies
  - Capture management off
  - R wave dropped to 4.5mV
    - Within normal limits
- PIEGM Displays intermittent loss of ventricular capture
- Urgent clinic review requested

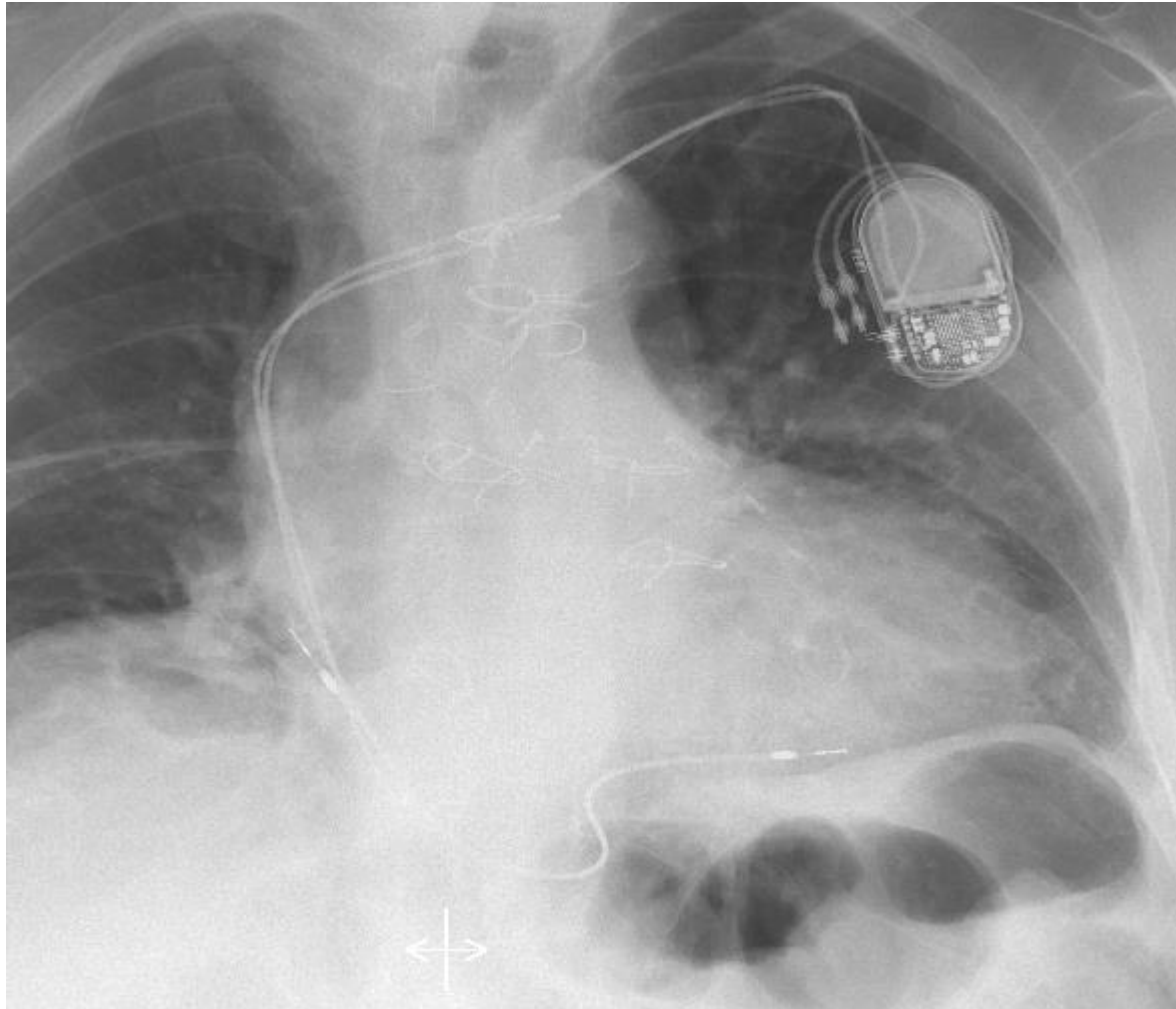
# PIEGM



# Post Implant Xray



# Clinic Xray

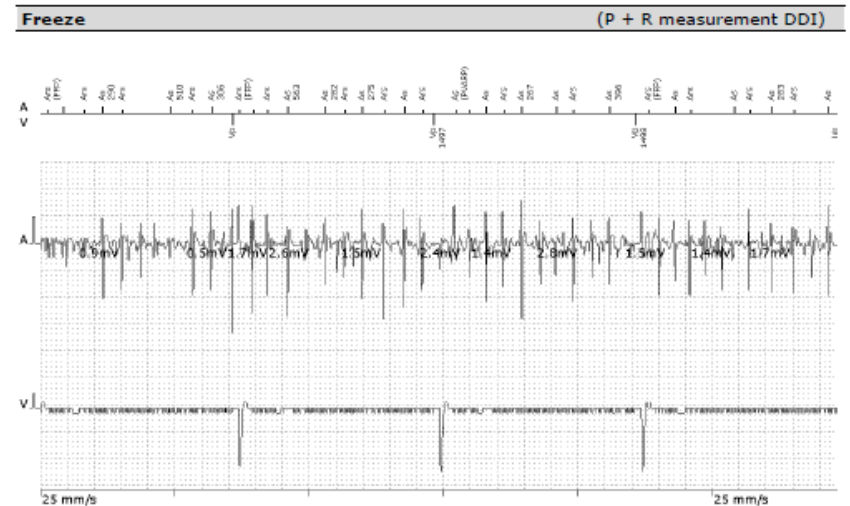
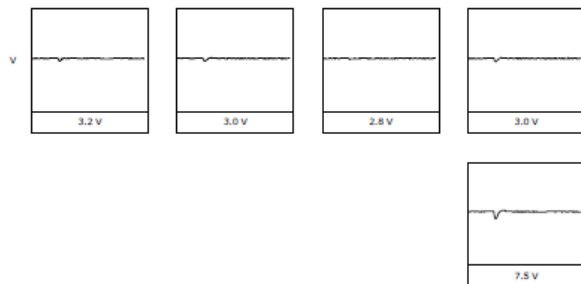


# Clinic Appt

- Threshold risen to 3.0v @ 0.4mV

- Pt had AF and become PPM dependent @ 40ppm

Test - Pacing threshold	
<b>Test program</b>	
Mode	Ven. VVI
Basic rate [bpm]	90
AV delay [ms]	
Upper tracking rate [bpm]	
	<b>A</b> <b>V</b>
Start amplitude [V]	7.5
Pulse width [ms]	1.5
Pacing polarity	BIPL
<b>Test settings</b>	
Print setup [mm/s]	OFF
Pulses	2
<b>Selected value</b>	
Threshold [V]	3.0
Threshold test display	IEGM





# Remote Monitoring.....

- Allows greater flexibility for staff and patients
- Could enable device clinics to operate a 7 day service
- Helpful to an ageing population
- Ability to detect lead and device issues earlier than clinic based follow up alone
- Is not infallible
  - Requires specialist staff

