

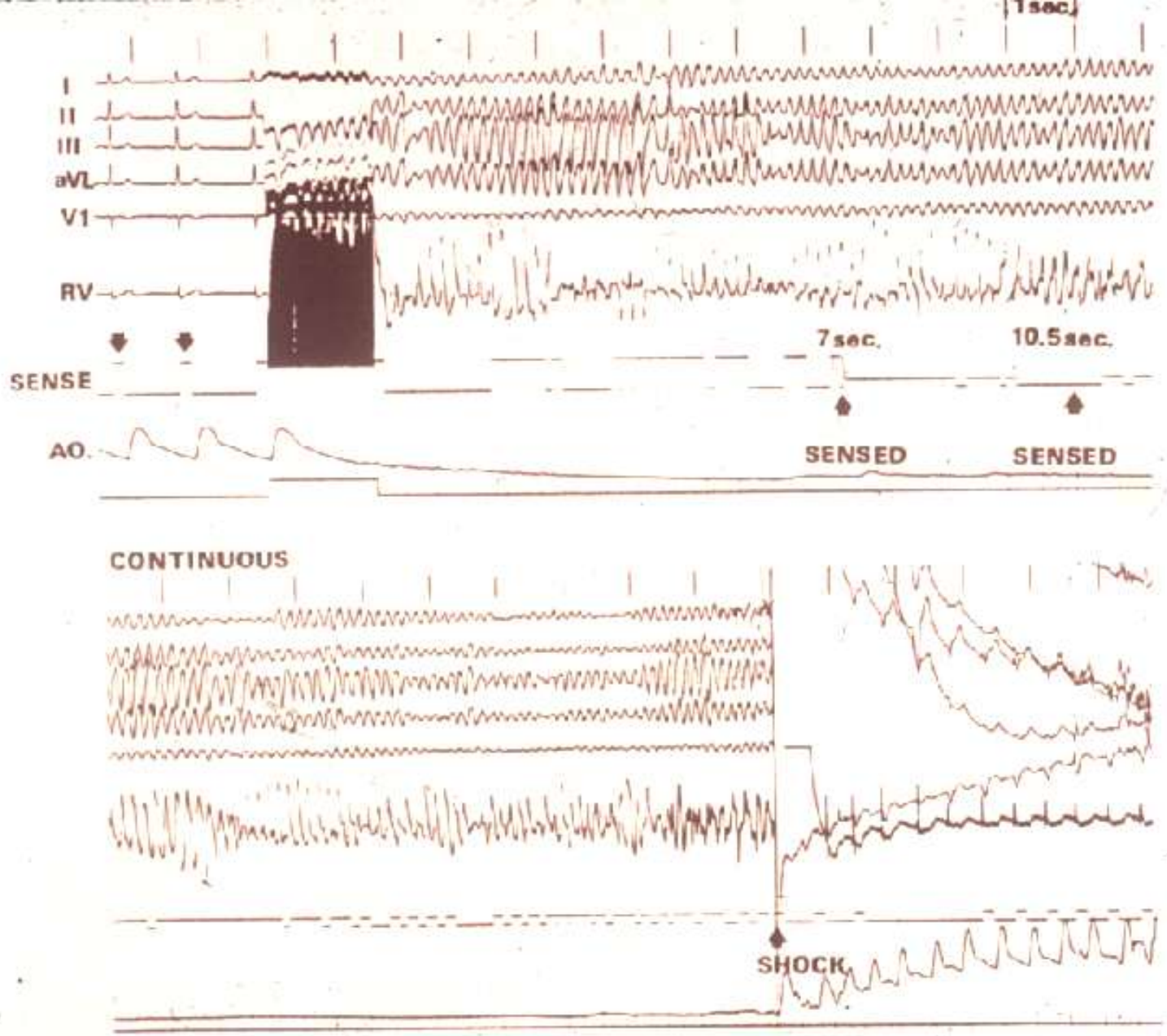
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Glasgow Royal Infirmary and
West of Scotland Heart & Lung Centre
Golden Jubilee National Hospital

Management Of Inappropriate
Shocks In ICD Patients:
**NON-ARRHYTHMIC CAUSES:
RECOGNITION AND MANAGEMENT**

October 2011

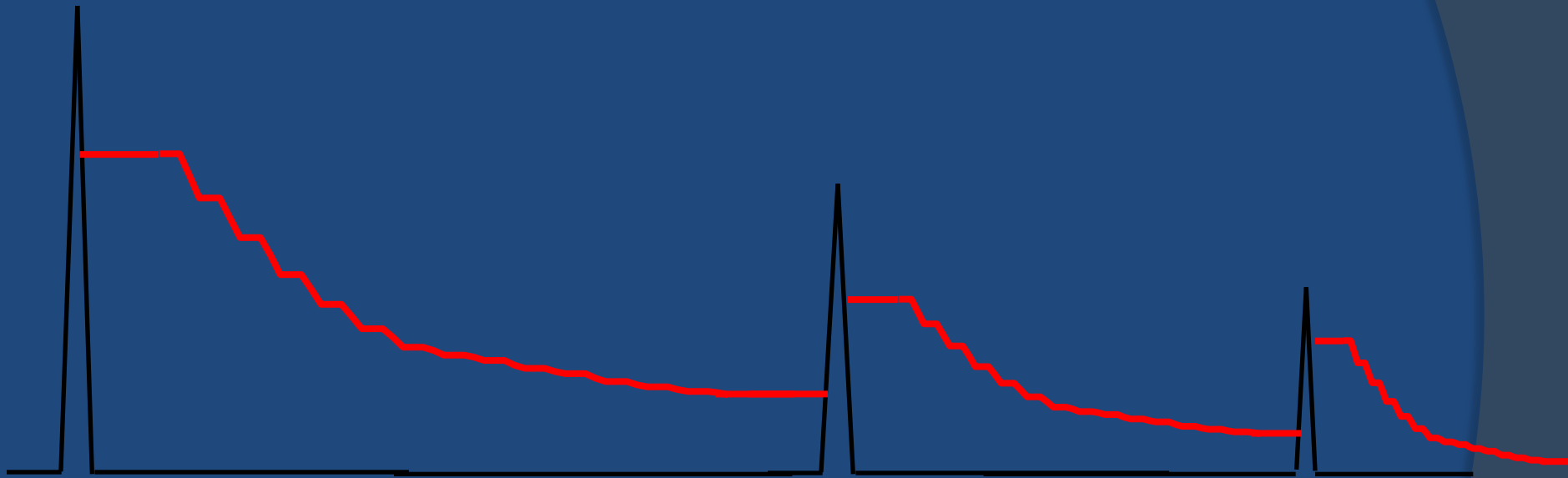
Acknowledgements

- ◉ **Jackie McLachlan**, Glasgow Royal Infirmary
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Mirowsky et al 1980 New Engl J Med

ICD Troubleshooting: Automatic Gain Control (AGC)



Sensing automatically adjusts on a beat-to-beat basis



VS 1105 VS 1030 VS 1128 VS 335 VF 290 VF 198 VF 148 VS 1075 VF 48 Epsd

End of Episode 00:12

report



VF Rx 1 Defib 35.1 J

Your life in

The ultimate



your pocket

digital device



Wilson Greatbatch - RIP 27 September 2011

- “of the first 16 Chardack-Greatbatch devices implanted, 10 had wire breakages, five had premature battery failures, one had an electric component failure and three caused infections”



Obituary, Daily
Telegraph, 28/9/11

Complications of ICDs

- 154 consecutive ICD implantations (39 non-thoracotomy); perioperative mortality 1.3%
- 37% had late postoperative problems
- 21 required system revision within 3 years
 - 3 electrode fractures, 2 adapter malfunctions, 3 undersensing, 5 coil migrations, 5 increased defibrillation thresholds, 3 pulse generator failures (1 infection)
- 32 patients had inappropriate shocks

O'Nunain *et al* 1995; *Circulation* **91**: 204

Complications of ICDs

- ⊙ 61 epicardial, 79 nonthoracotomy systems; followed up for 25 ± 19 months
- ⊙ 10 complications (16.4%) in epicardial group:
 - Patch crinkling in 6, insulation break in 2, adapter defect in 2
- ⊙ 8 complications (10.1%) in transvenous group:
 - subcut patch fracture in 2, SVC lead dislodgement in 2, insulation break in 1, connector defect in 1
- ⊙ Abnormalities either detected by routine CXR or associated with multiple shocks

Korte *et al* 1995; *PACE* 18: 2053

Complications of ICDs

- 144 consecutive new ICD implants (non-thoracotomy leads); follow-up 21 ± 15 months
- 41 pts (28%) had 1 or more complications
 - No perioperative deaths, no infections
 - 7 lead problems in 6 pts (4%) - lead migration in 4
 - Severe bleeding in 5 (3%)
 - Pneumothorax (2), high DFT (2), antibiotic allergy (2), DVT, CVA, generator malfunction (1 each)
 - Inappropriate shocks in 23 pts (16%) - for SVT (13), non-sust VT (7), myopotential oversensing (3)

Grimm *et al* (1999) *PACE* 22; 206-11

MADIT-II Study – inappropriate shocks

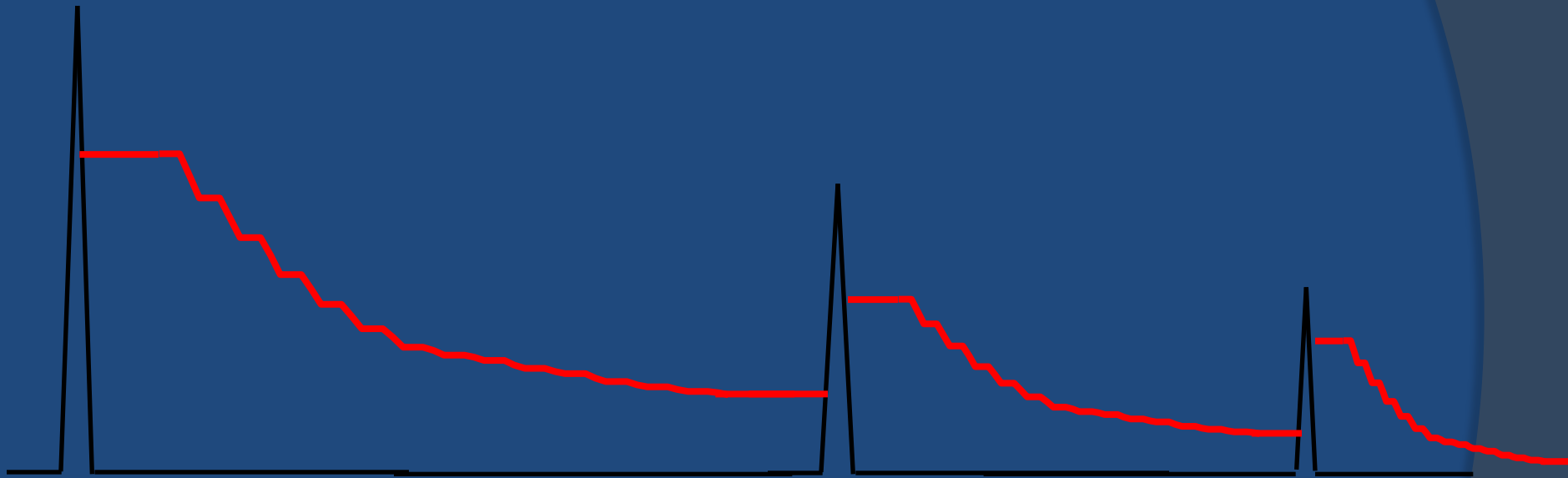
- ⊙ Inappropriate shocks occurred in 83 (11.5%) of the 719 MADIT II ICD patients
- ⊙ Of 590 total shocks, 184 (31.2%) were inappropriate
- ⊙ Causes:
 - AF – 44%
 - SVT – 36%
 - Abnormal sensing – 20%
- ⊙ Patients with inappropriate shocks had ↑ mortality risk (HR 2.29, p=0.025)

Daubert et al, *JACC* 2008; **51**; 1357-65

Causes of sensing problems in ICDs

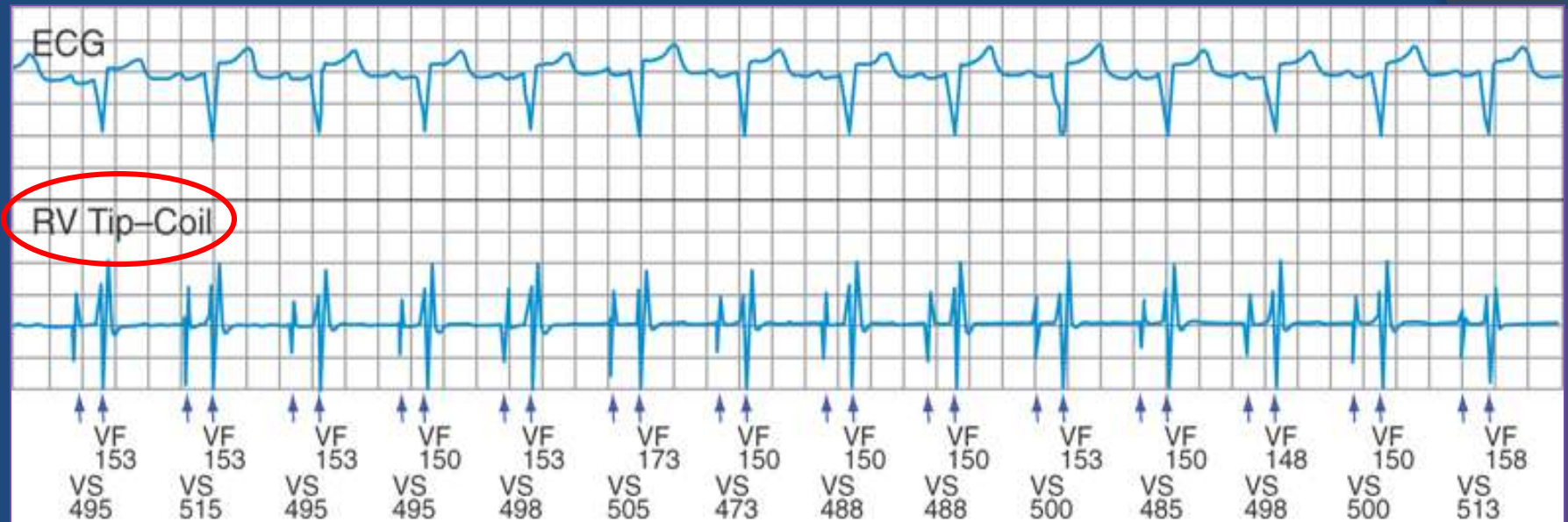
- ⊙ Arrhythmias
- ⊙ Myopotential oversensing
 - Connector problems
 - Insulation fracture ($\downarrow Z$)
 - Conductor fracture ($\uparrow Z$)
- ⊙ Cardiac potential oversensing
 - T wave oversensing
 - (P wave oversensing)
 - QRS double-counting (early CRT devices)
- ⊙ Extraneous interference

ICD Troubleshooting: Automatic Gain Control (AGC)



Sensing automatically adjusts on a beat-to-beat basis

P wave oversensing



Diagnosis: P-wave oversensing

Reason: P-wave oversensing caused by the close proximity of the RV coil to the right atrium, resulting in ICD sensing VS and VF intervals

Solution: Reposition the ventricular lead to eliminate the problem

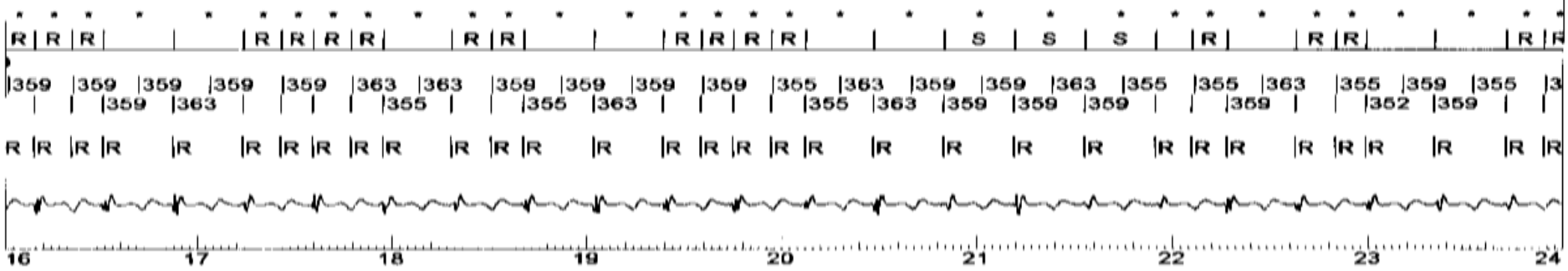
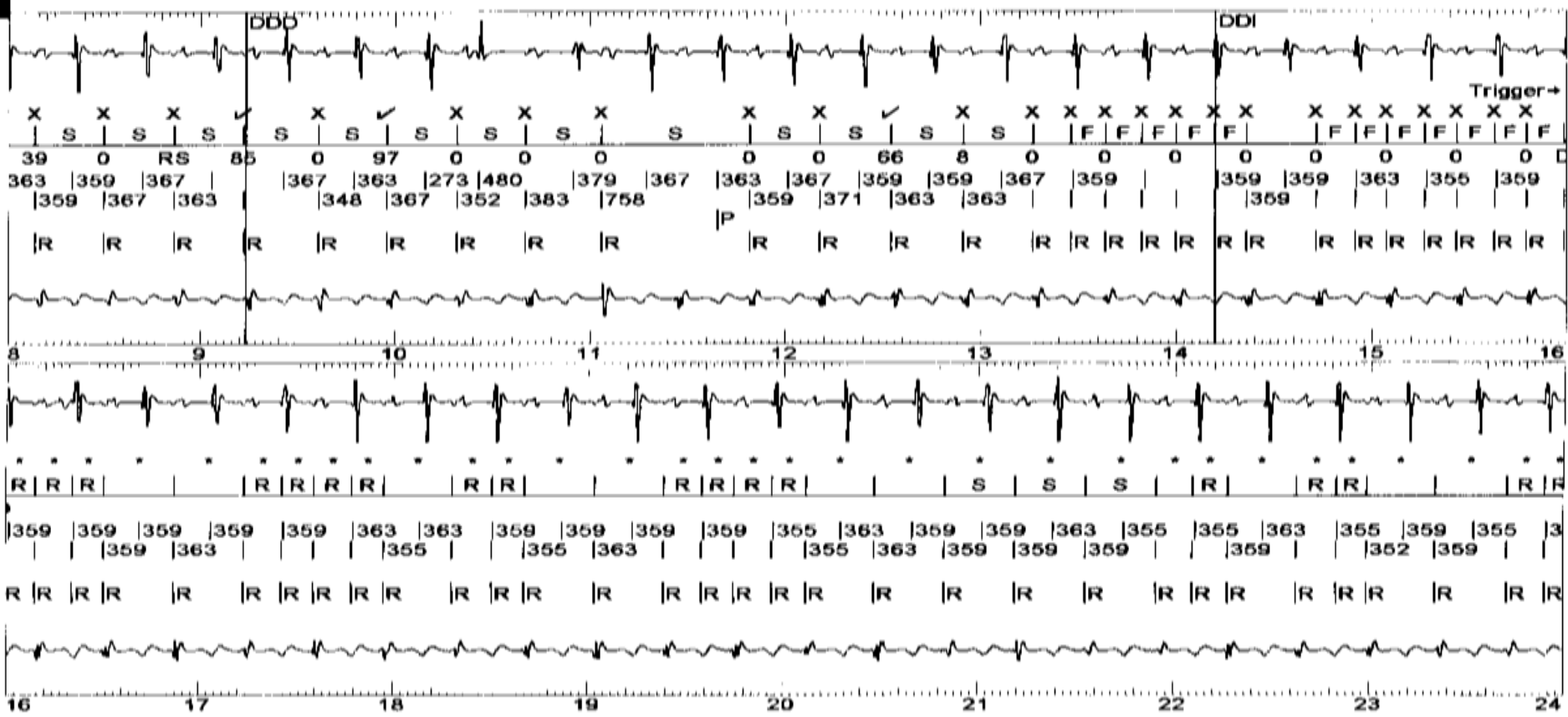
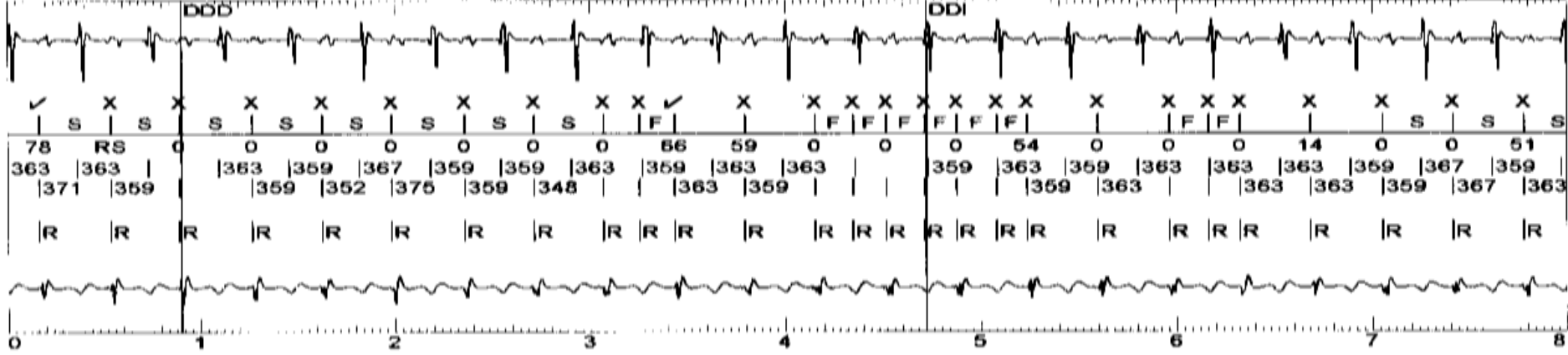
T-wave oversensing

Date of Visit: 10-May-2011 08:37:15
SW002 Software Version 7.0
Copyright © Medtronic, Inc. 2005



T wave oversensing

- ⦿ Can often be avoided by checking for T wave sensing at implant
- ⦿ But can occur *de novo* late after implant
- ⦿ Can be a problem, especially in LQTS patients



T wave oversensing

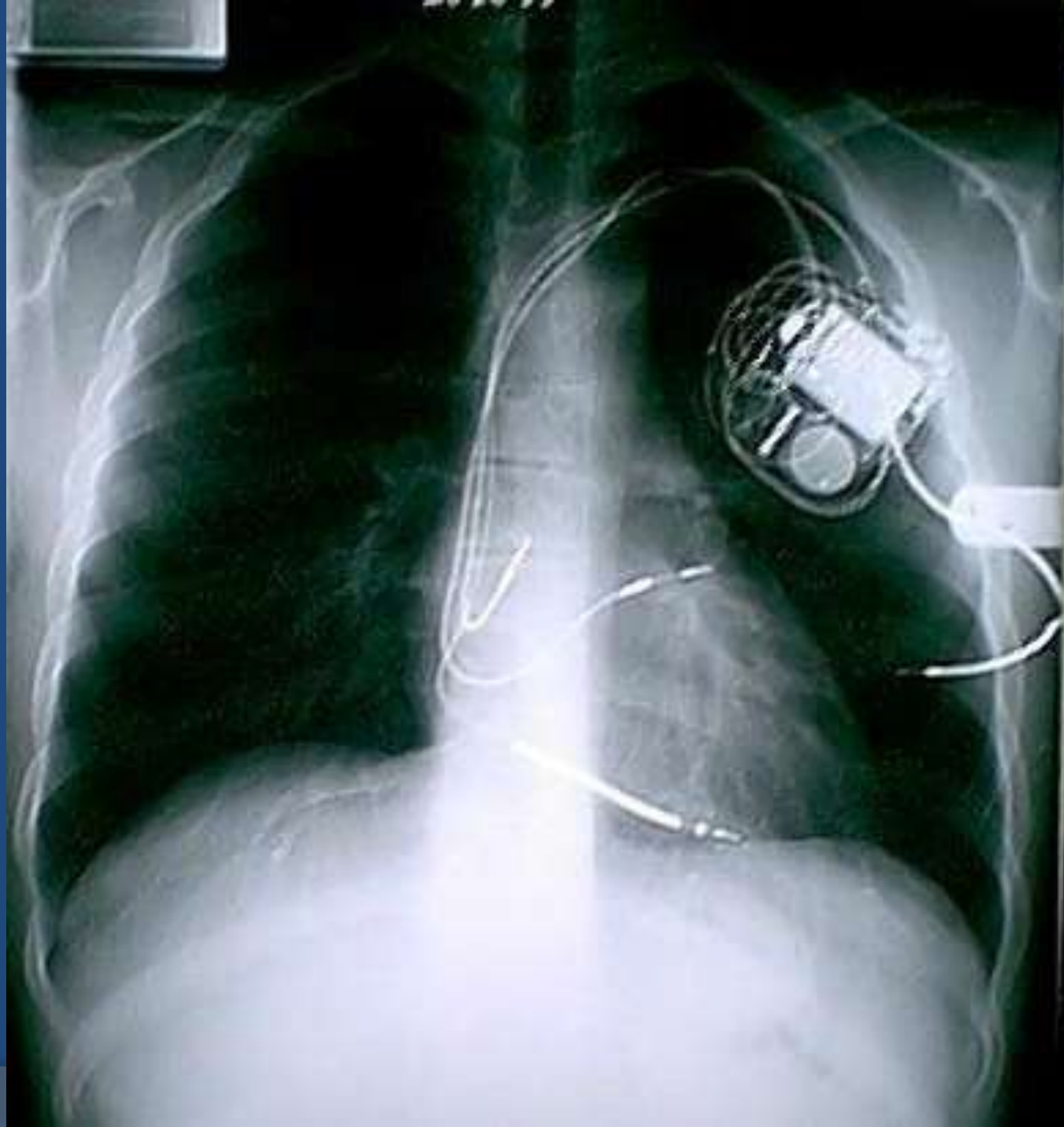
- ⊙ Can lead to inappropriate shocks ...
- ⊙ On the T wave !
- ⊙ But very seldom fatal
 - Concept of “Upper limit of vulnerability”
 - ULV approximates to DFT
 - High-energy shocks (above ULV) do not induce VF

T wave oversensing – case study

- ◎ CA ♂ born 1982
- ◎ VF arrest age 16
- ◎ Early dilated cardiomyopathy diagnosed
- ◎ ICD implanted 1998
 - Medtronic Gem DR
 - Youngest patient world-wide with this device; featured in company's glossy brochure
- ◎ Multiple inappropriate shocks
 - Sinus tachycardia with T wave oversensing & double-counting
- ◎ Unable to exercise; β -blockers made him feel “like a zombie”

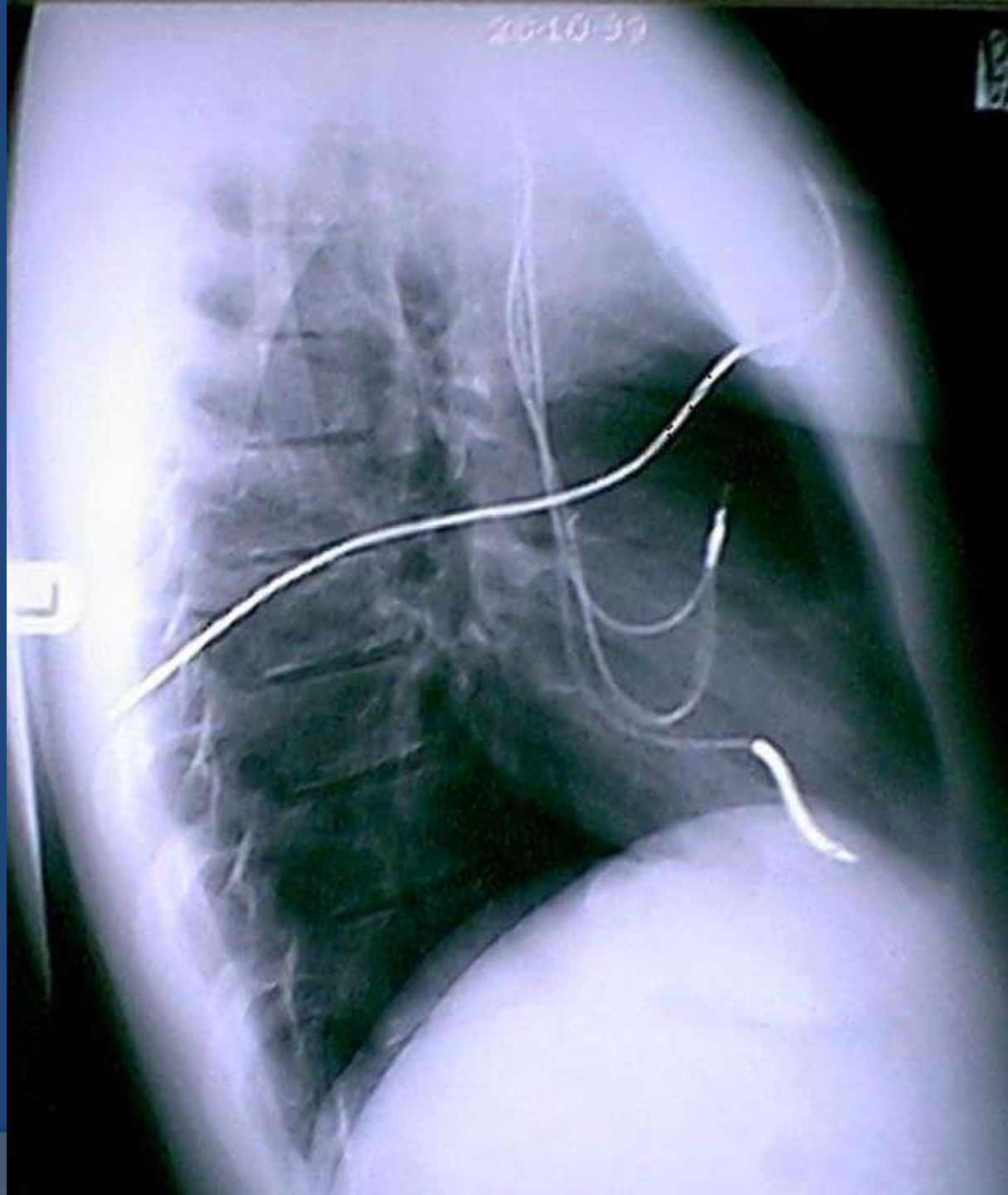
T wave oversensing – case study

- ⊙ Problems continued despite changing programming / refractoriness / sensitivity
- ⊙ 1999 – routine clinic review
 - Series of 6 x 35J shocks the previous afternoon
 - Initially denied symptoms, then admitted circumstances ...
- ⊙ Reached age 17 ... and became my problem!
- ⊙ Clinical and ethical dilemma...
- ⊙ October 1999 – lead revision
 - Separate sensing lead in RVOT
 - Lower amplitude T waves at this site
 - Isoproterenol infusion during implant with direct telemetry of electrograms
- ⊙ High DFT – subcut array lead implanted

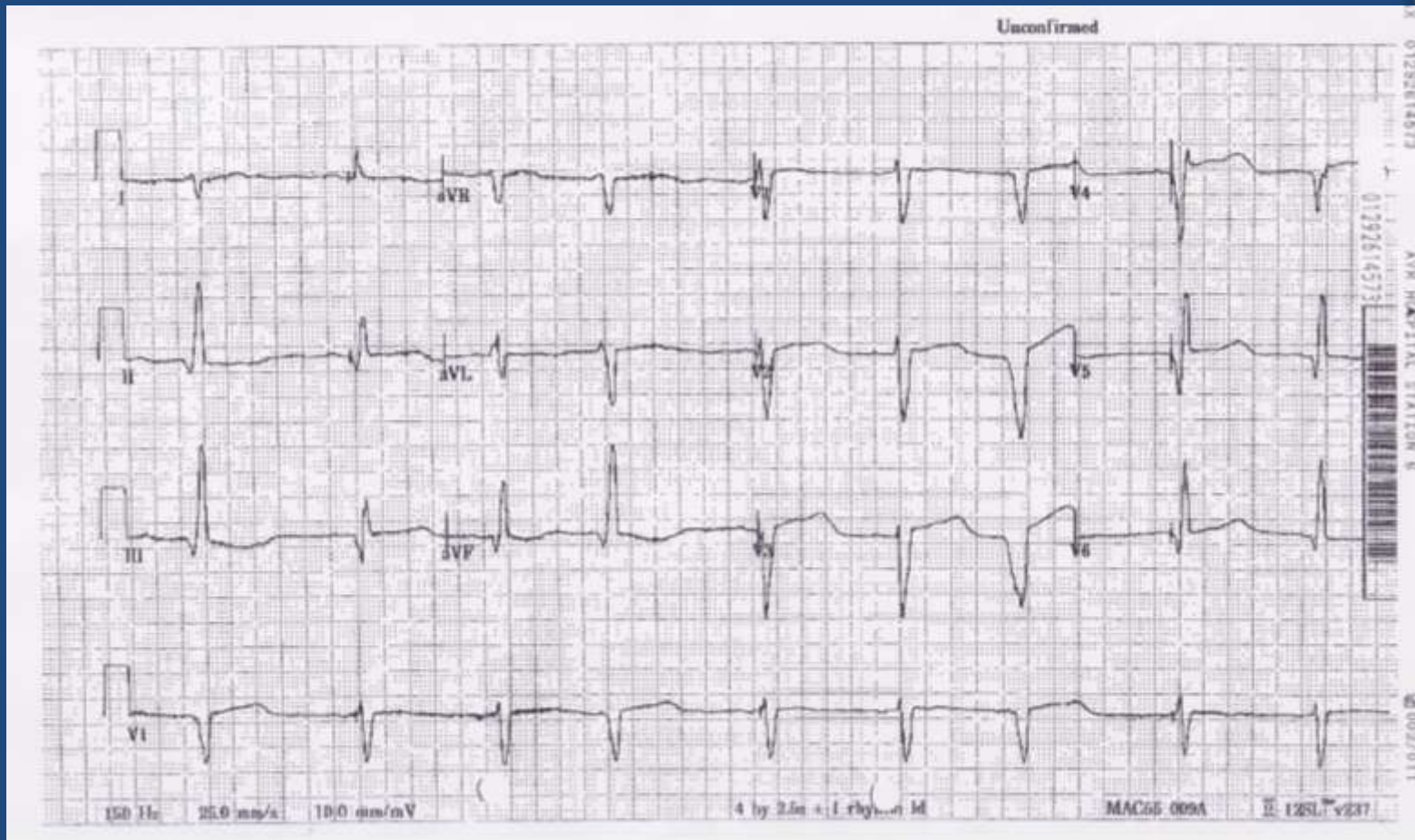


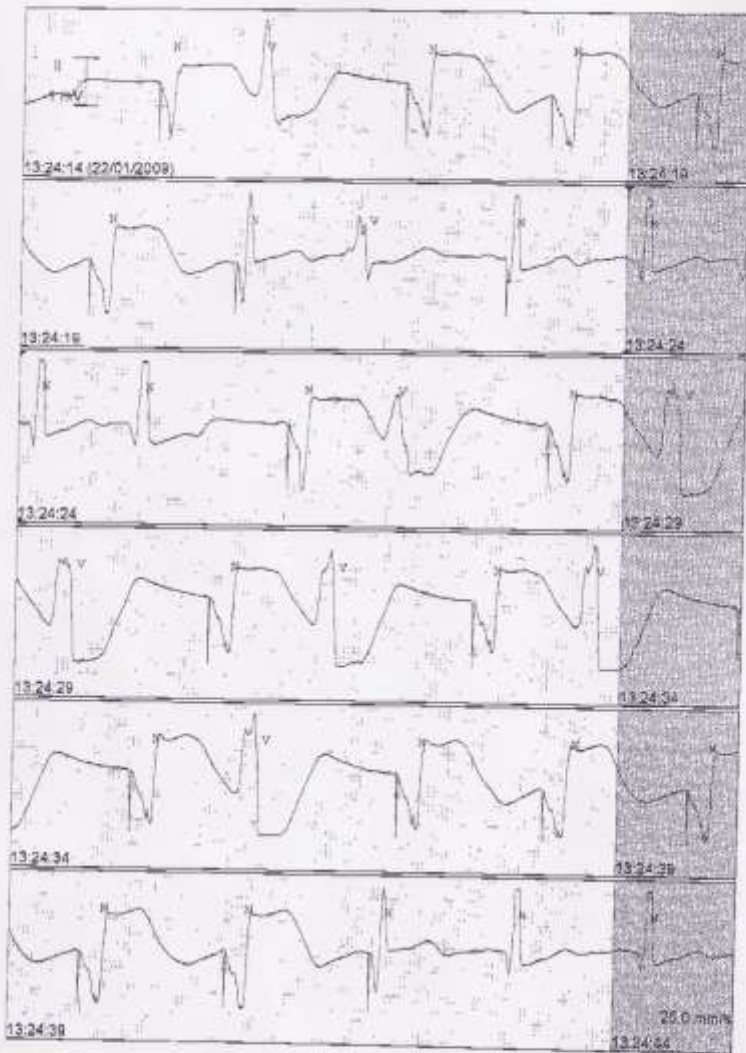
27-10-59

13



T wave oversensing – arrhythmic and non-arrhythmic problems



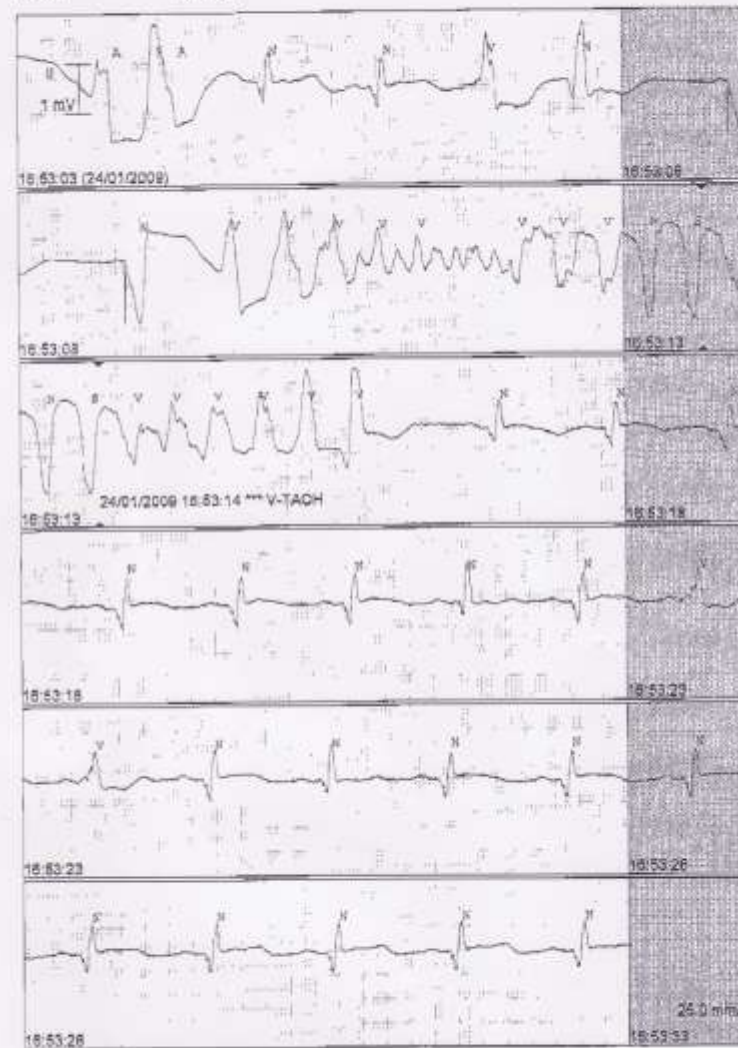


Alarm Review

24/01/2009 16:53:14 *** V-TACH

HR 68

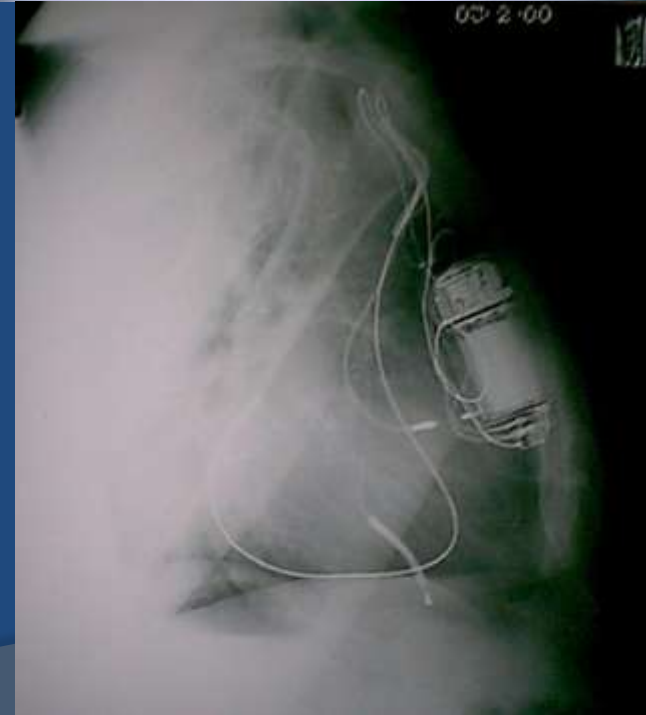
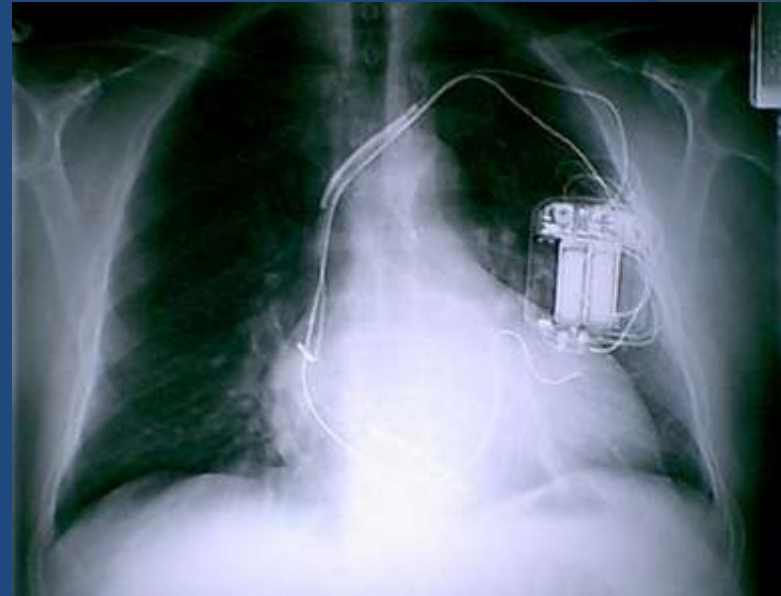
PVC 16



QRS

Double-counting

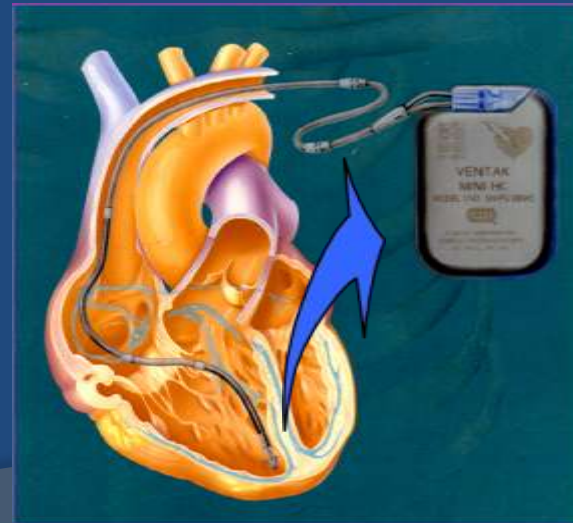
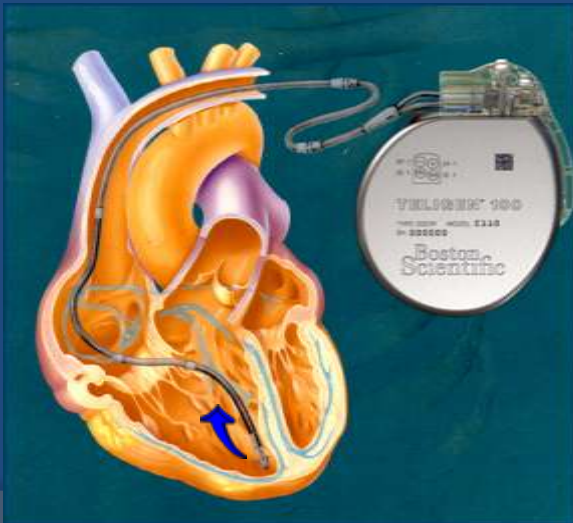
- Only seen in earliest CRT-D models (1999-2001)
- Common sensing between RV and LV leads
- LV lead signal late in QRS
- Need to check for “double-counting” at implant



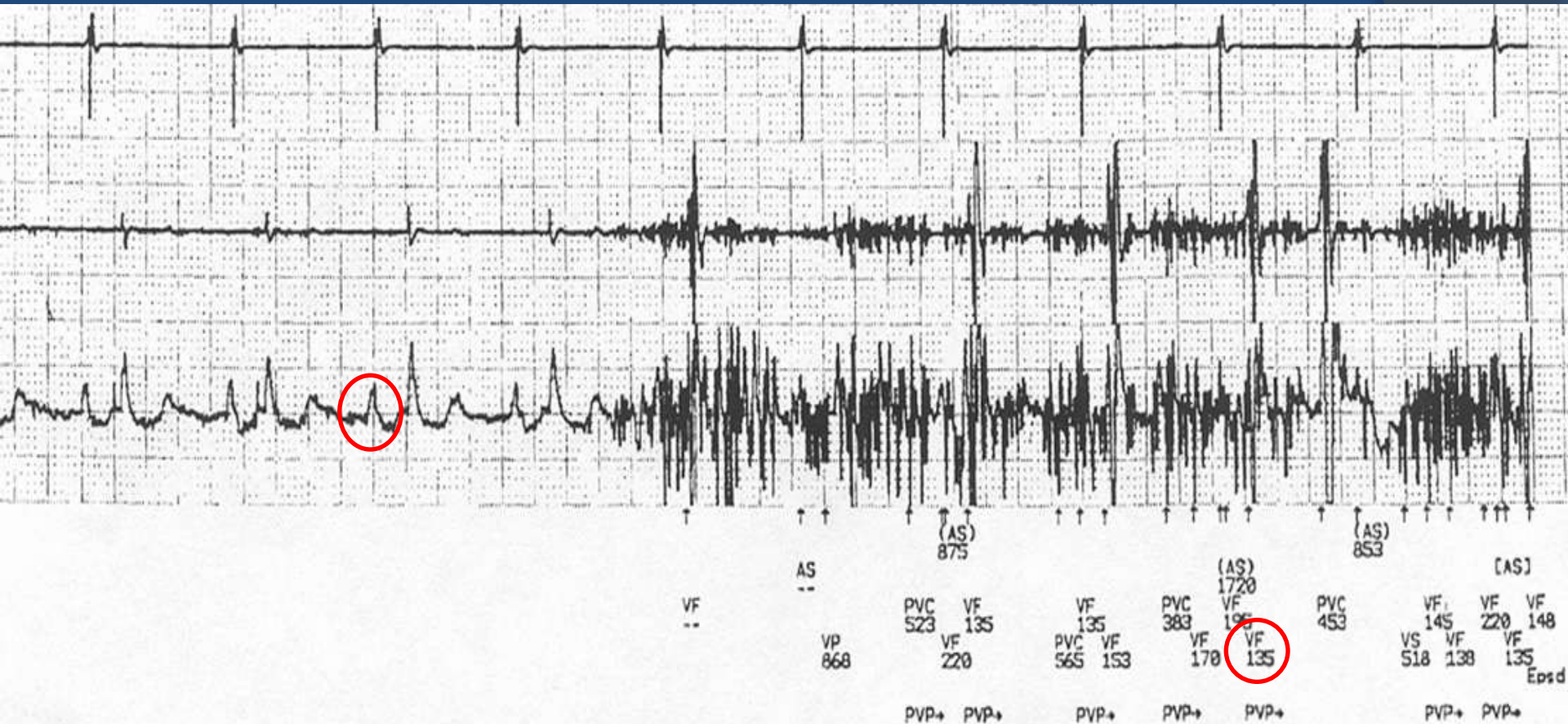
Noise

Noise due to reversed connections

- Only a problem with dual-coil leads with integrated bipolar sensing
- Normal sensing –
 - RV tip to RV coil
- IF DF-1 electrodes are plugged in wrongly, sensing occurs from RV tip to SVC coil and can



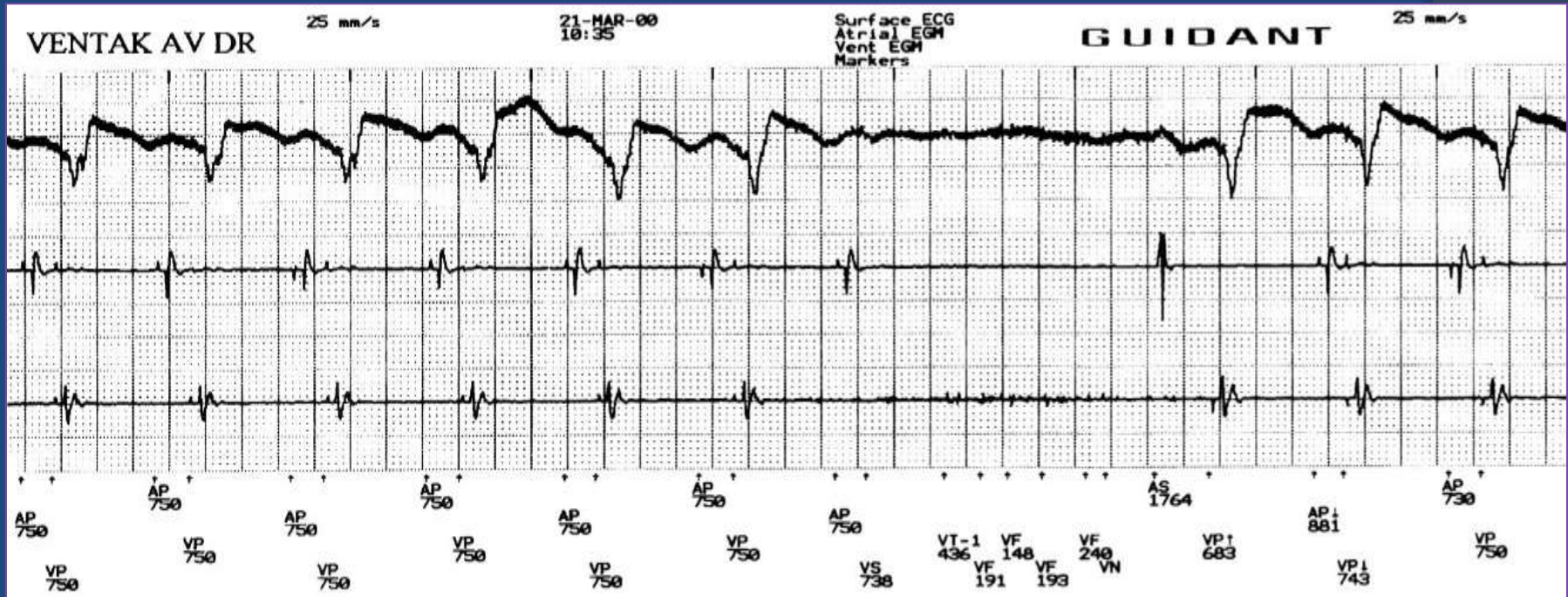
ICD Troubleshooting: Reversed Connections



Isometrics result in artifact on both the rate and shock EGMs with unusually large p-waves on shock EGM

Diaphragmatic sensing –

Integrated bipolar system, pacing-dependent patient



Diagnosis: Oversensing of diaphragmatic myopotentials during deep inspiration

Reason: With deep inspiration, diaphragmatic myopotentials are sensed as VT and VF events
During VT/VF detection, pacing is suspended, resulting in a pause
This patient had received a shock during deep breathing exercises

Solution: Reprogramming from “nominal” to “least” sensitivity eliminated the problem



VS 1105 VS 1838 VS 1128 VS 335 VF 198 VF 148 VF 238 VF 138 VS 1875 VF 288
 End

End of Episode 0012

End of Report



Termination

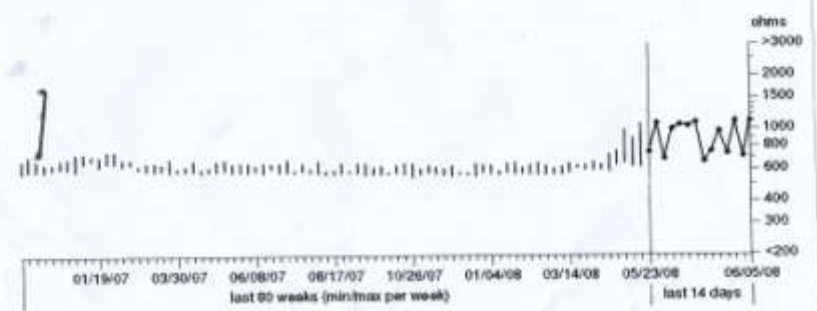
ICD Model: Maximo VR 7232
 Serial Number: PRN6194573

Jun 05, 2008 11:07:39
 9979 Software Version 1.0
 Copyright Medtronic, Inc. 2003

Lead Performance Trends Report Page 1

Ventricular Pacing Impedance

At Implant	704 ohms	Highest	1088 ohms
Last	1104 ohms	Lowest	544 ohms



01/19/07 03/30/07 06/08/07 08/17/07 10/26/07 01/04/08 03/14/08 05/23/08 06/05/08
 last 90 weeks (min/max per week) | last 14 days

Predictors of ICD lead malfunction

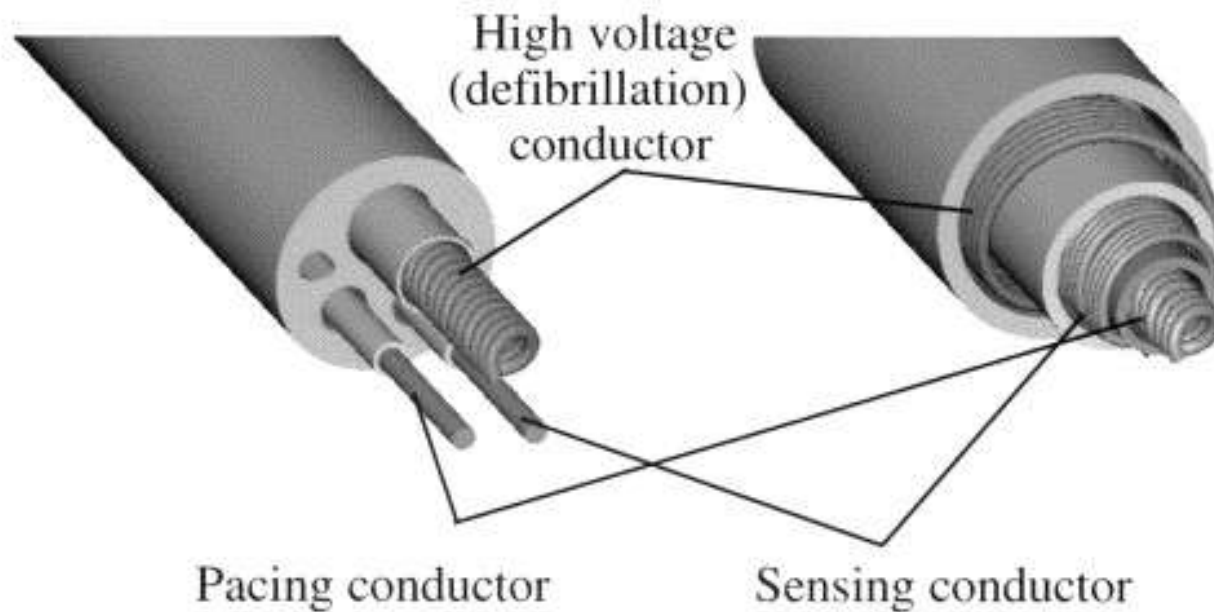
- ⦿ 369 patients (391 ICD leads) implanted at Mayo clinic pre-1998
- ⦿ Routine defibrillation testing annually!
- ⦿ 18 lead failures in 17 patients
- ⦿ Four years post-implant, cumulative lead failure rate was 18% (95% CI 8-27%)
- ⦿ Abdominal ICD location was only independent predictor of lead failure

Luria et al *Am J Cardiol* 2001; **87**: 901-904

- ◎ Of 18 lead failures:
 - Lead fracture in 6 (33%)
 - Insulation failure in 3 (17%)
 - Pacing or sensing failure in 9 (50%) without obvious displacement or structural issue
 - Inappropriate shocks in 7 patients (39%); others found at routine testing
 - 4/6 fractures & 2/3 insulation failures presented with inappropriate shocks
- ◎ All patients with pectoral implants & fracture . Insulation break had coaxial lead design (MDT Transvene)
- ◎ no structural failures with multilumen design leads (GDT Endotak, MDT Sprint)

Multilumen
lead body design

Coaxial
lead body design

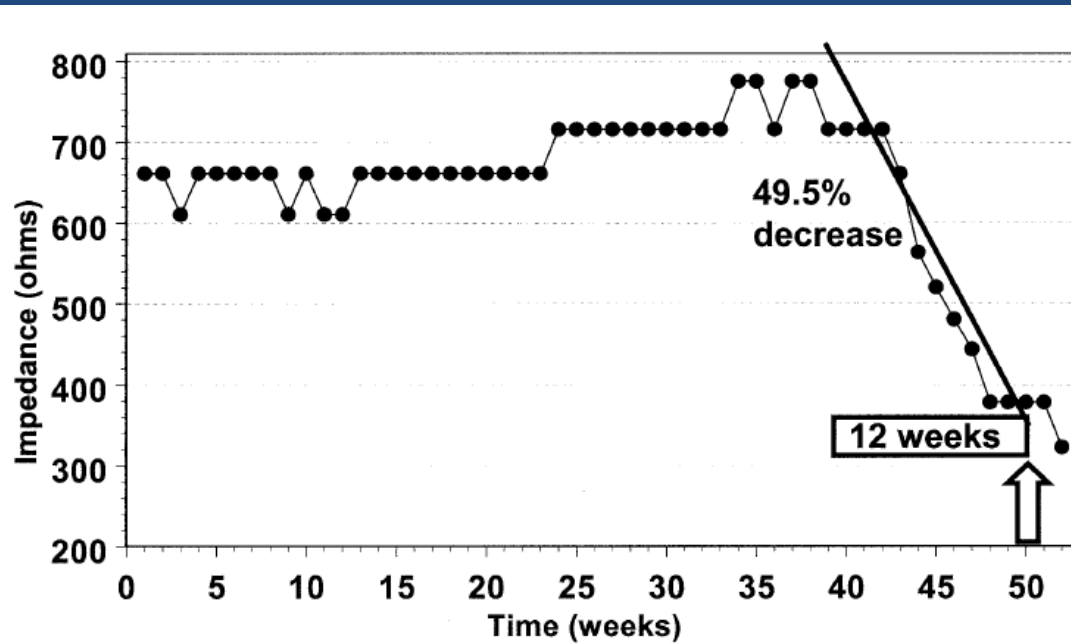
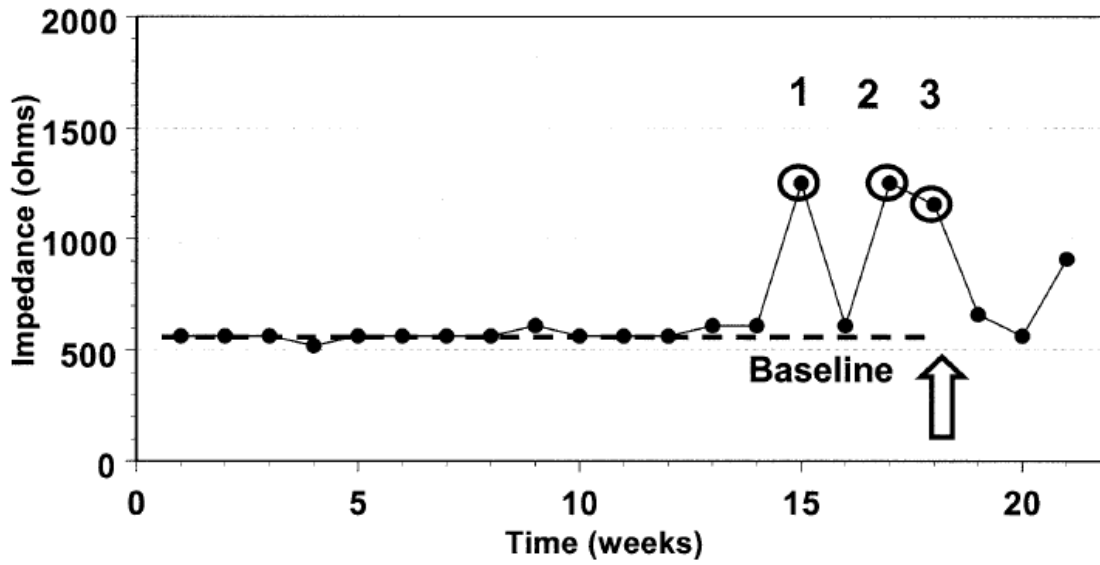


Luria et al *Am J Cardiol* 2001; **87**: 901-904

An algorithm to predict ICD lead failure

- ⊙ 2 measures of oversensing & 1 measure of abnormal impedance
 - Oversensing: RR interval counters <140ms, NSVT c/I <200ms
 - Impedance (Z) tracked daily or weekly
 - Decrease in Z or outlier value
- ⊙ 696 patients studied, 29 had clinical lead failure with 6 ± 9 inappropriate shocks per patient
- ⊙ Algorithm (2 of 3 measures abnormal): 83% sensitive, 100% specific

Gunderson et al *JACC* 2004; 44: 1898-1902



- ◎ 11 of 29 patients (38%) had abnormal Z before an inappropriate shock
 - 3 had multilumen leads and 8 had coaxial leads
 - Mean time from abnormal Z to inappropriate shock was 8.1 +7.2 weeks (range 1.4 to 22 weeks)

Gunderson et al *JACC* 2004; **44**: 1898-1902

Electromagnetic Interference



Study of Pacemaker and Implantable Cardioverter Defibrillator Triggering by Electronic Article Surveillance devices (SPICED TEAS)

- ⊙ Magnetic fields emitted by “shoplifting gates” may interfere with implanted devices
- ⊙ 25 adult volunteers & 50 with PMs or ICDs studied
- ⊙ Interference in 48/50 systems
 - asynchronous pacing, atrial oversensing, PMT, V oversensing with inhibition, etc
- ⊙ “Don’t lean, don’t linger”

McIvor et al *PACE* 1998 **21**: 1847

Management of Lead failures

Recent MHRA Advisories / Recalls

- Medtronic Sprint Fidelis Survival rates
- Model 6949 Dual coil active fixation
 - 90-93% at 5 years
 - Higher failure rate in younger patients (age <40)
- Model 6948 Dual coil passive fixation
 - 94.4% at 5 years
- Model 6931 Single coil active fixation
 - 87-93% at 5 years

Management of Lead failures

Recent MHRA Advisories / Recalls

- Medtronic Sprint Fidelis (6930, 6931, 6948 & 6949)
- If a Fidelis pace-sense conductor fracture has occurred, we recommend implanting a new high-voltage lead, + extraction of Fidelis lead. It is no longer a recommended option to implant a pace-sense lead while maintaining use of the Fidelis HV conductors

Months after a Pace-Sense Conductor Fracture

	0	6	12	18	21
N (leads)	182	120	88	63	54
HV conductor survival %	100	98.7	89.0	80.3	77.7

Medtronic, April 2011
MHRA Alert 19 May 2011

Management of Lead failures

Recent MHRA Advisories / Recalls

- ⦿ St Jude Riata
- ⦿ Risk of abrasion of silicone rubber insulation
 - Lead-can; lead-lead; subclavian crush; “inside-out” abrasion caused by movement of conductors within insulation
- ⦿ Majority of abrasions occur within 27 months
- ⦿ Overall survival rate 95.3% at 8 years

SJM Field Safety notice 15 December 2010

MHRA Medical Device Alert 16 December 2010

Conclusions

- ⦿ Inappropriate shocks & lead failures continue to pose problems
 - May be solved by smarter algorithms
 - T waves are low frequency, myopotentials are high frequency compared to QRS signals
- ⦿ Remote monitoring systems are likely to prove useful in identifying \uparrow or \downarrow Z prior to inappropriate shocks
 - We should probably be intervening earlier!
- ⦿ Younger patients at higher risk
 - Role for ICD without intracardiac leads in young patients?
- ⦿ T wave oversensing is an occasional problem
- ⦿ External electromagnetic interference is rare