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Advanced ICD Concepts

ICD System Evaluation

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- This presentation is provided with the understanding that the slide content must not be altered in any manner as the content is *subject to FDA regulations*.
- This presentation is to be used in conjunction with other resource material including the applicable Boston Scientific device *physician's manual* and any *implant accessories instructions* for use.
- This presentation is not intended to replace implant training.
- Proper surgical procedures and techniques are the responsibilities of the medical professional.
- If this presentation is not used in its entirety, the following information must be included:
 - Appropriate Indications
 - Contraindications
 - Warnings
 - Precautions and Adverse Events

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When we complete this program you will be able to:

Identify possible causes of:

- Inadequate Defibrillation Thresholds (DFTs)
- Nondetection
- Nonconversion
- Asymptomatic Therapy

Identify troubleshooting measures to aid in:

- Assessment
- Possible Resolutions

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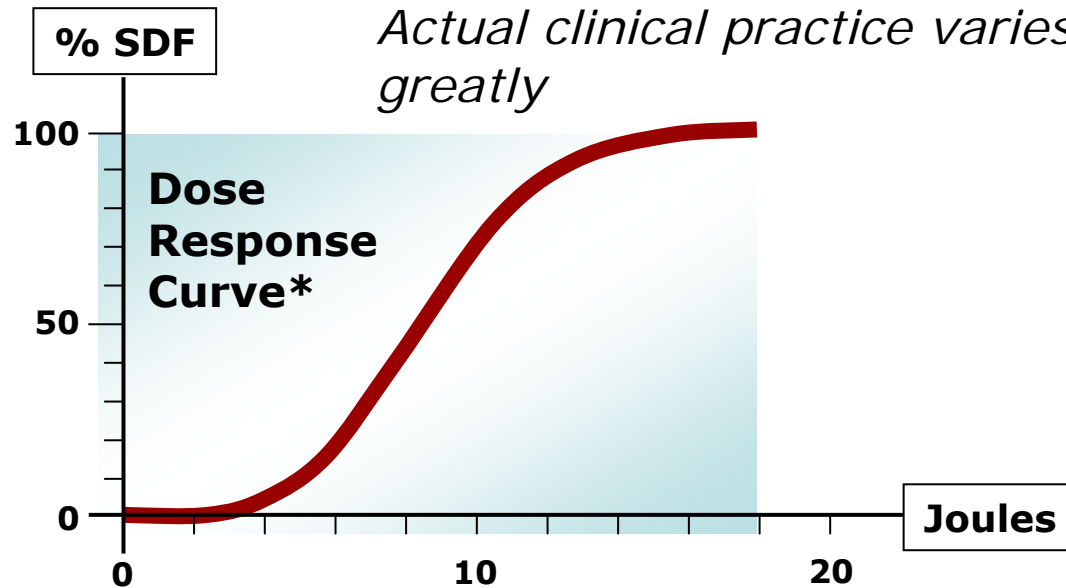
Summary /
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- Each situation should be evaluated based on patient assessment and hospital / physician standard practices
- Refer to ICD device instruction manual for complete and further operating information

Defibrillation is a Statistical Phenomenon:

Recommendation: Minimum of 2 successful shocks with 10J safety margin

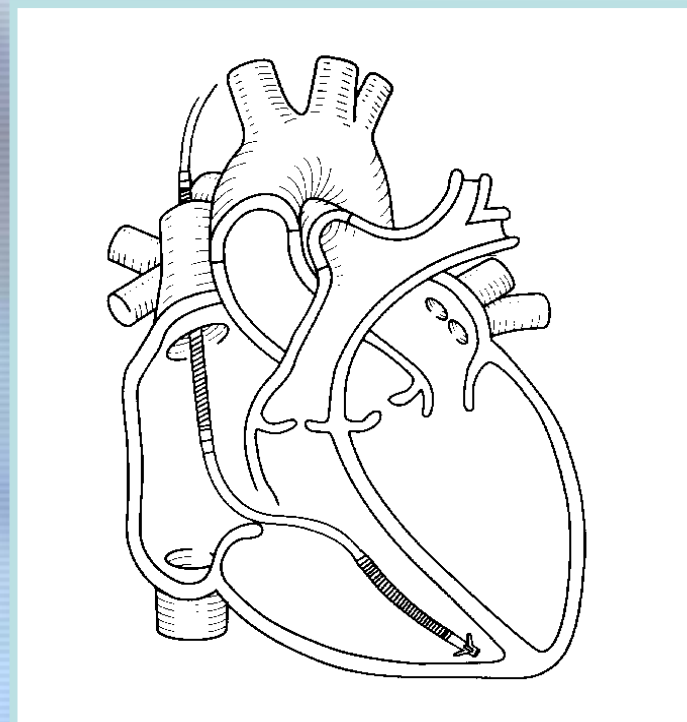
Actual clinical practice varies greatly



*Troup, P. Current Problems in Cardiology - Implantable Cardioverters and Defibrillators. 1989, Vol XIV, #12

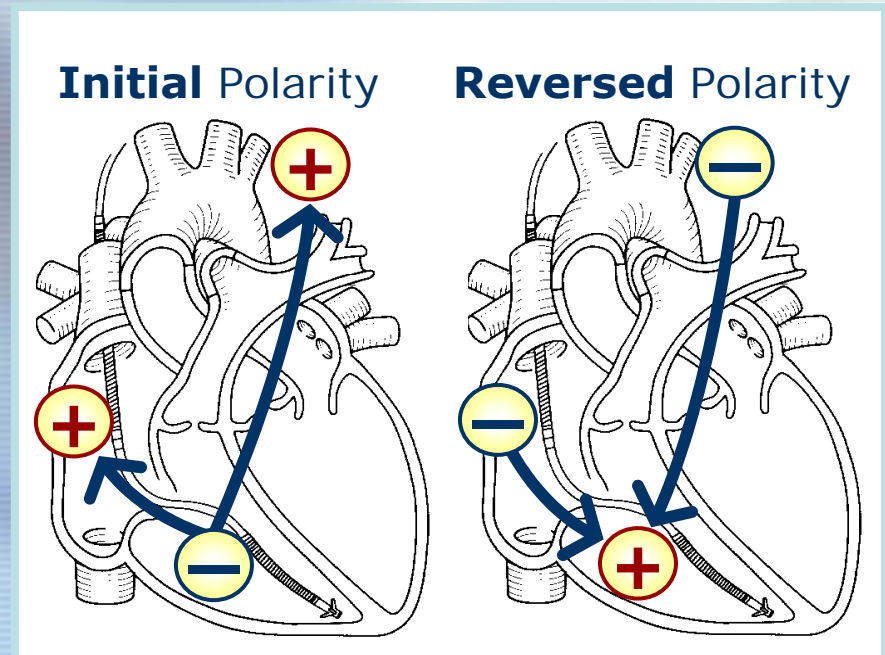
Reposition the Lead:

- Success of lead alone highly dependent on positioning
- Best positioning may be deep into RV apex with distal coil up against septum



Reverse Polarity of Defibrillation Electrodes

- Most successful with **monophasic** waveforms
- May decrease DFT's with **biphasic** waveforms
- Polarity is programmable in device-based testing



Test Alternate Waveform Configuration

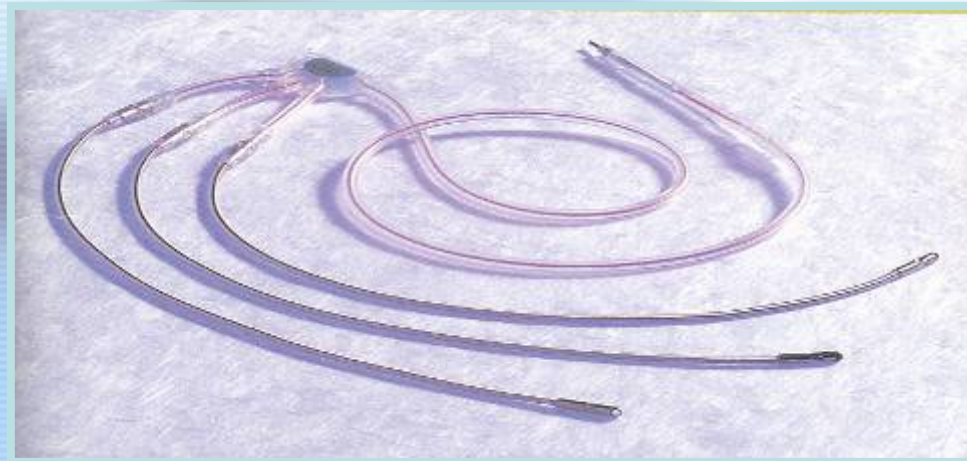
Try **monophasic** waveform if biphasic unsuccessful

Therapy Features	
Shocks	
Waveform	Monophasic
Polarity	INITIAL
Committed Shock	NO

Try **biphasic** waveform if monophasic unsuccessful

Therapy Features	
Shocks	
Waveform	Biphasic
Polarity	REVERSED
Committed Shock	NO

Implant DFT Modifier



- Subcutaneous Lead Array (SQ array)
- Subcutaneous Patch Lead (SQ patch)
- Decreases system resistance & alters current vector
- Multiple configurations possible

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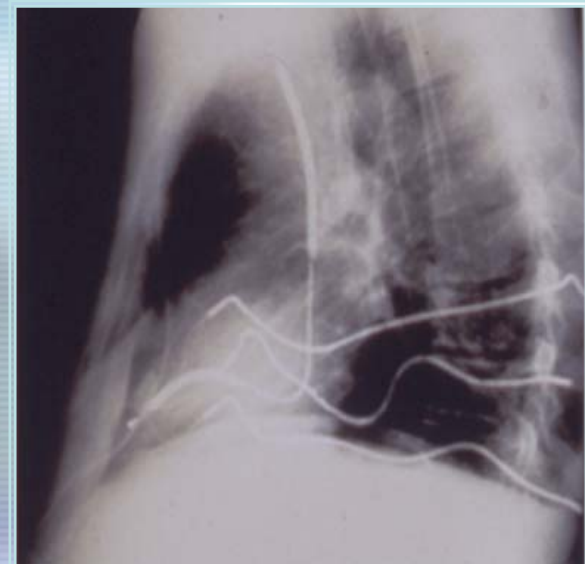
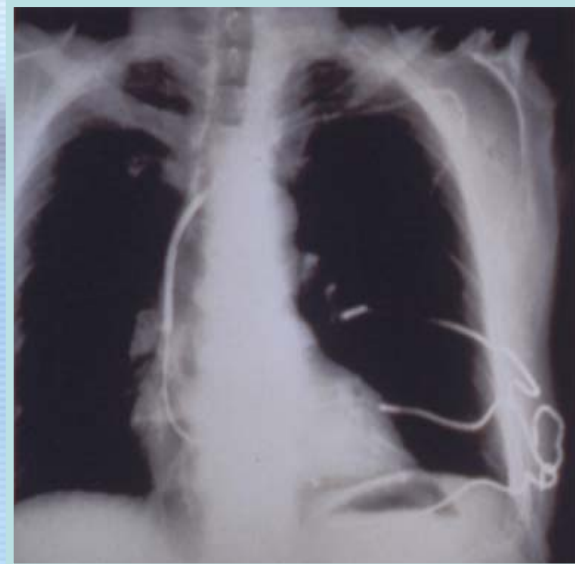
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Implant DFT Modifier



- AP view and lateral view of Implanted ENDOTAK Lead and an implanted SQ Array Lead
- SQ Array Electrode Elements are fanned from the lateral chest insertion site around towards the posterior chest

High DFTs: Evaluate Other Factors

- Certain antiarrhythmic drugs known to increase DFTs

- *chronic Amiodarone* use can raise DFTs
- Amiodarone may need to be *discontinued* or taken at a *reduced dosage* with testing repeated at some future date



- Anesthesia may sometimes elevate DFT's

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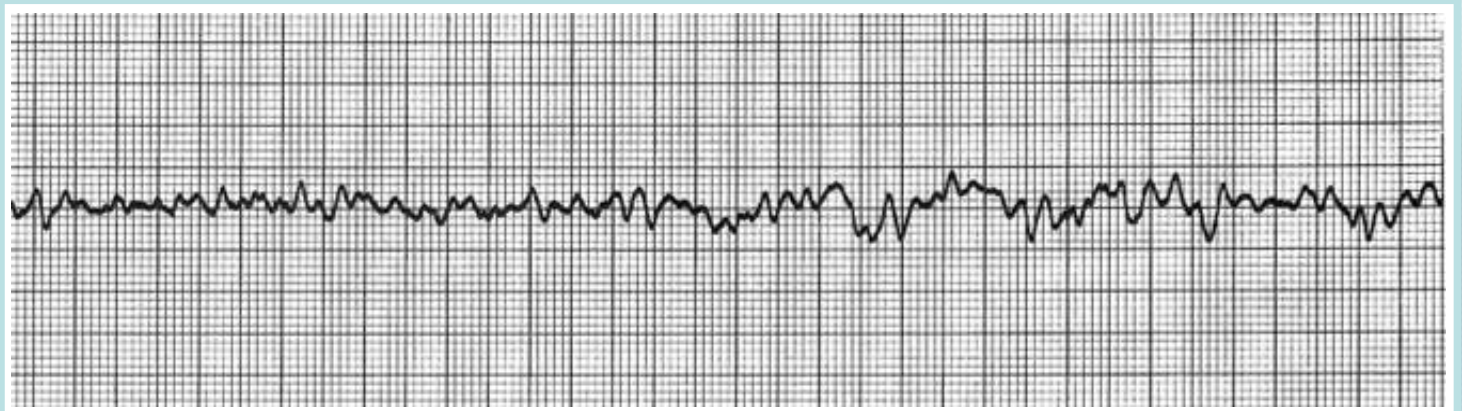
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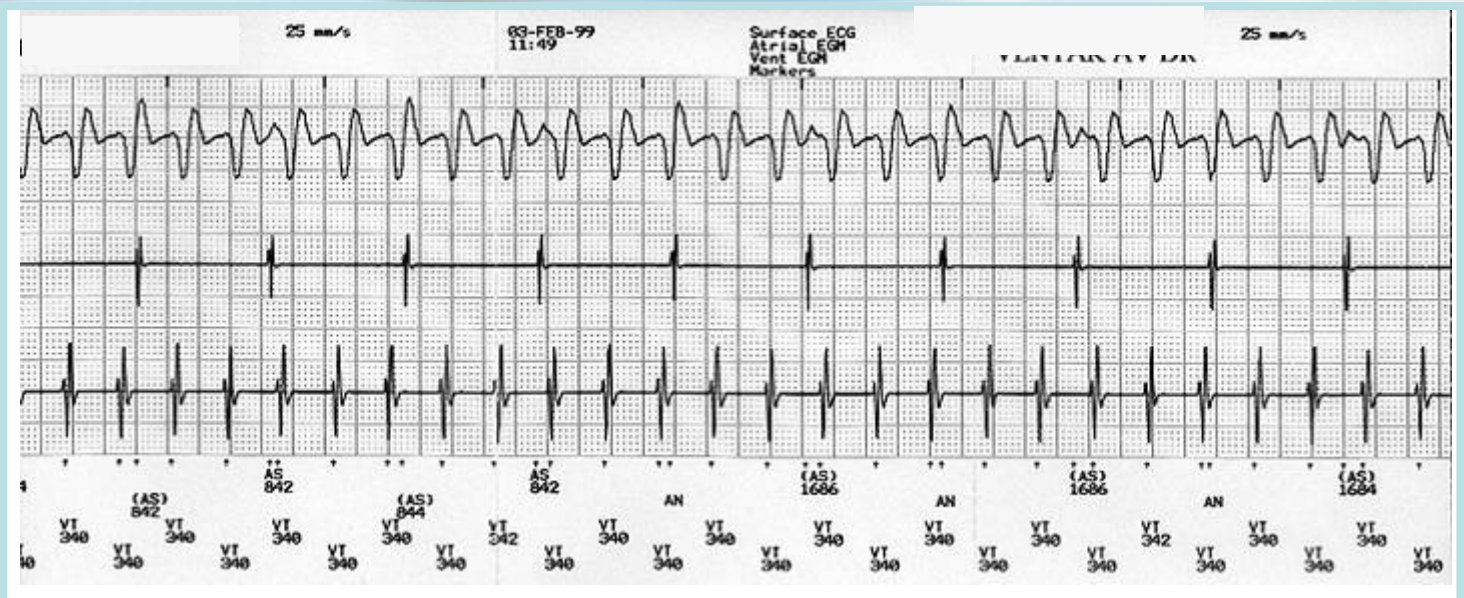
Failure to Sense or Improper Classification of Arrhythmia



- Induced arrhythmias during implant or EP study
- Spontaneous arrhythmias post-implant

Evaluate Event Markers from Induction Episode

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Provides real-time assessment of device's sensing of arrhythmia & classification of sensed intervals

Verify Rate of Arrhythmia is in Zone

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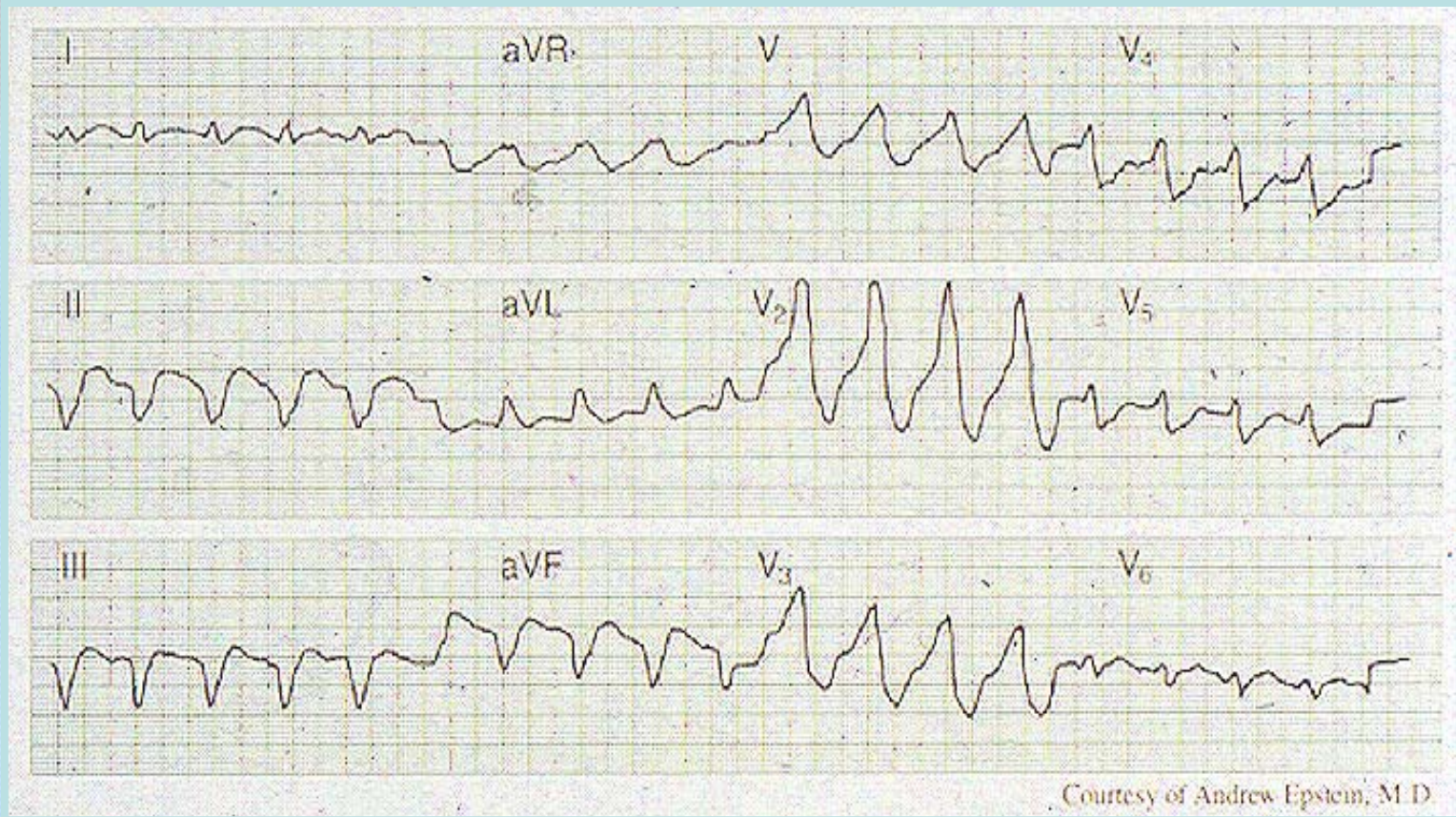
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Device Parameter Summary		Tachy Mode =	Monitor+Therapy
VF	200 bpm 1.0 sec		31J/ 31J/ 31J X 3
VT	120 bpm 2.5 sec	Onset = OFF Stab Inhibit = OFF Stab Shock = OFF AFib Rate Thres = OFF V Rate > A Rate = -- SRD = -- min:sec	ATP1x 3 ATP2x OFF 3J/ 31J/ 31J X 3

Lowest Zone Rate:

- 10 bpm less than MVT rate
- 30 bpm less than PVT rate

Slow Dysrhythmia



Courtesy of Andrew Epstein, M.D.

“Drop out” is Undersensing of VF During Detection

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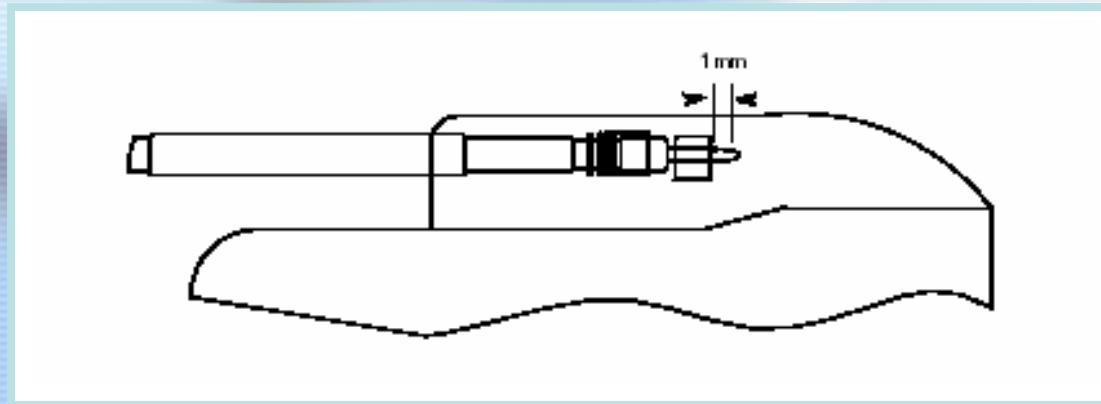
Evaluate Programmed Detection Enhancement

Programmed Initial Detection Parameters

```
>190    VF:  
>170    VT:  
>140    VI-1: Onset 9 % And  
          A Fib 200 bpm, Stability 10 ms  
          W.L. 255 0 00
```

- Detection enhancement criteria not satisfied
- Safety override feature(s) not programmed "ON"

Check Lead-to-Header Interface



- Rate-sensing electrode end(s) fully inserted beyond connector block
- Setscrews tight

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Verify Tachy Status is "Monitor + Therapy"

Parameters Report	
PG Configuration	
Tachy Mode	Off
Tachy Zones	3
Last Programmed	03-FEB-99 11:53

- No therapy delivery in "Monitor Only" or "OFF" mode
- Bradycardia pacing not affected by tachy status

Evaluate Beeping Tones for Appropriate Sensing

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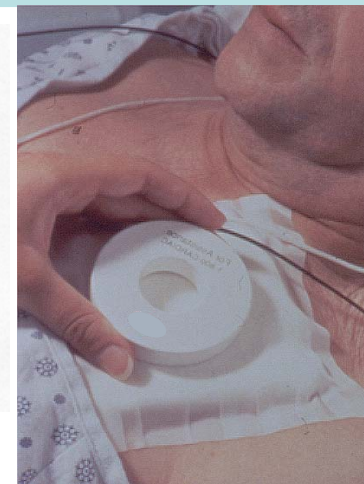
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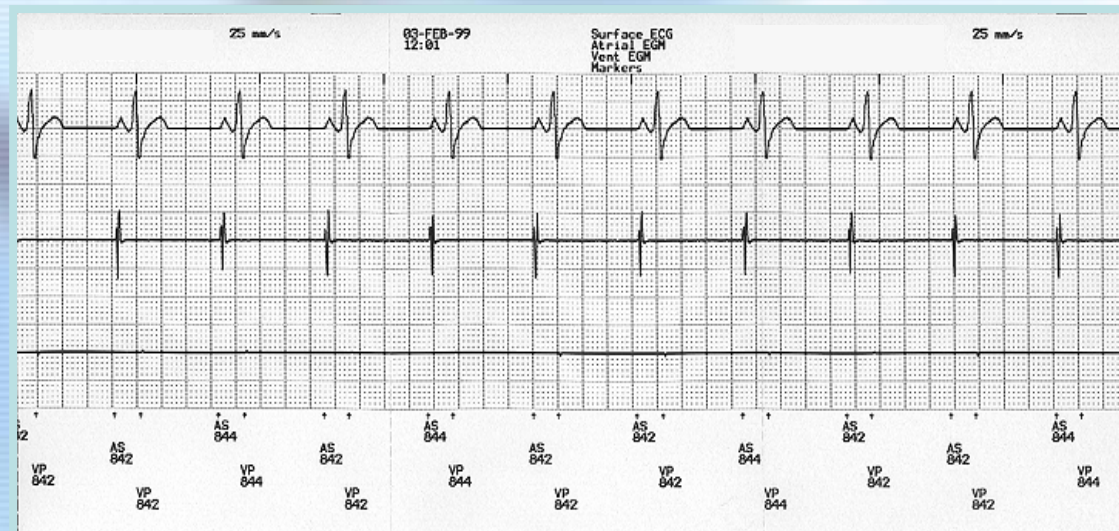
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Magnet/Beeper/EGM Functions	
Enable Magnet Use	ON
Change Tachy Mode with Magnet	OFF
Beep During Capacitor Charge	OFF
Beep on Sensed Ventricular Events and Paced Ventricular Events	ON
Beep when ERI is Reached	ON
Electrogram Storage	
Atrial	ON
Ventricular	ON
Shock	ON
Onset	ON



- Programmable beep-on-sense feature
- Magnet-induced tones

Evaluate Real-time Electrogram from Rate-sensing Electrodes



- Note presence or absence of R-wave signals
- Compare to real-time device electrogram recorded at implant

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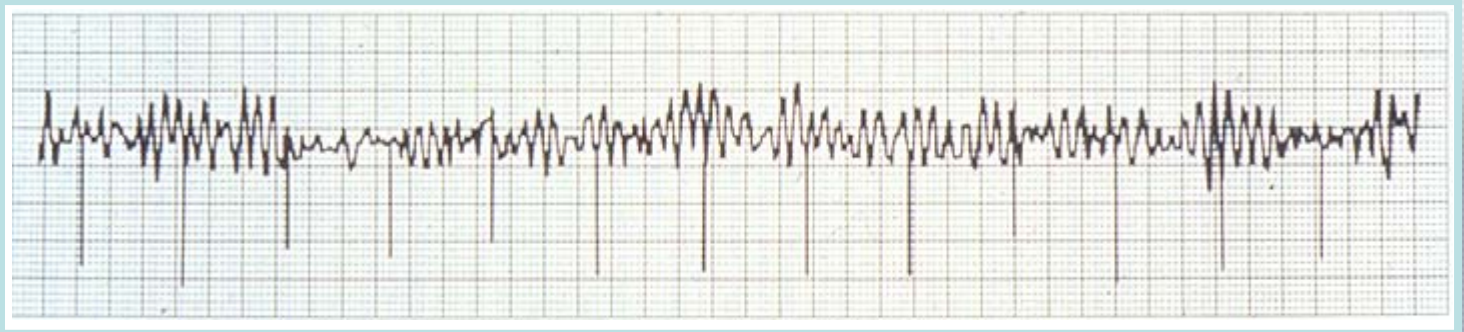
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Pacemaker Interaction



- If separate pacemaker implanted, check for interaction
- Pacing during arrhythmia may result in ICD sensing the pacing artifact instead of arrhythmia

Guidelines for ICD / Pacemaker

- 1** *Use* dedicated bipolar pacemaker
- 2** *Select* pacing leads(s) with close electrode spacing
- 3** *Use* screw-in pacing lead in ventricle in order to position pacing lead away from defibrillation lead rate-sensing tip
- 4** *Choose* pacemaker with high sensitivity to avoid pacing during VT/VF
- 5** *Set* pacemaker amplitude to lower possible setting while maintaining safety margins
- 6** *Test* for potential interaction during implant
 - *Pace* at maximum output during arrhythmia conversion testing to ensure appropriate detection
 - *Check* for multiple sensing during paced rhythm using beeping tones &/or event markers
 - *Assess* pacemaker for any reprogramming following shock from ICD

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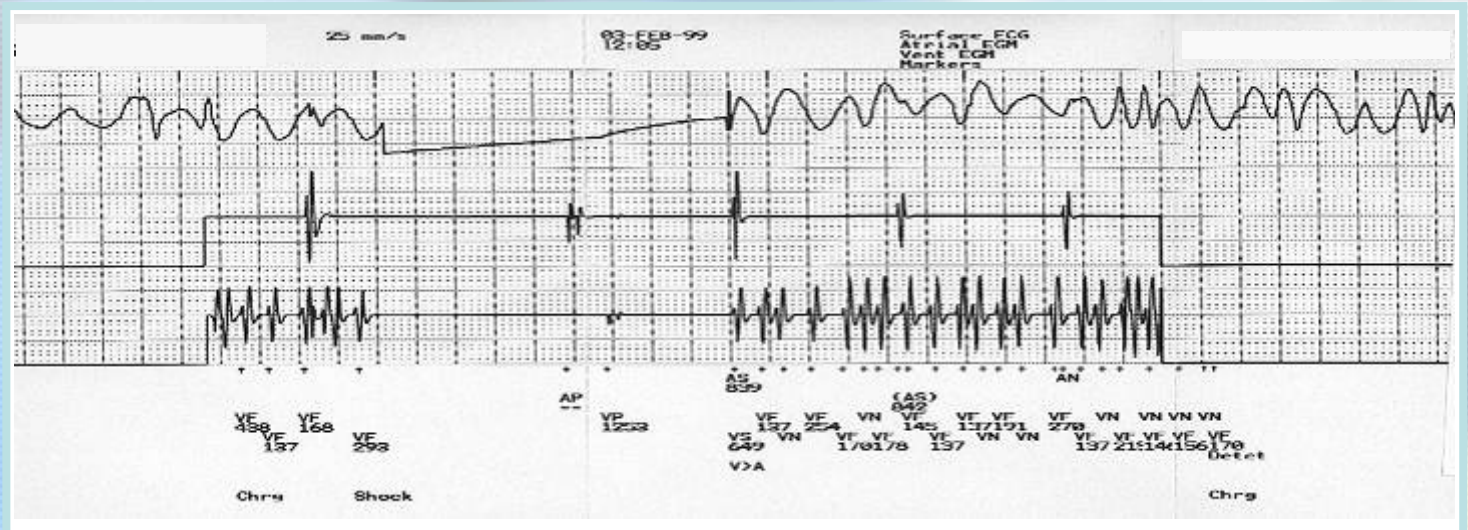
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X-ray: Evaluate Status of Lead(s) for Sensing

- Fracture
- Insulation Break
- Dislodgment
- Migration
- Incomplete insertion of lead(s) into header of pulse generator

Failure of a Shock to Convert Patient



- Induced arrhythmias during implant or EP study
- Spontaneous arrhythmias post-implant

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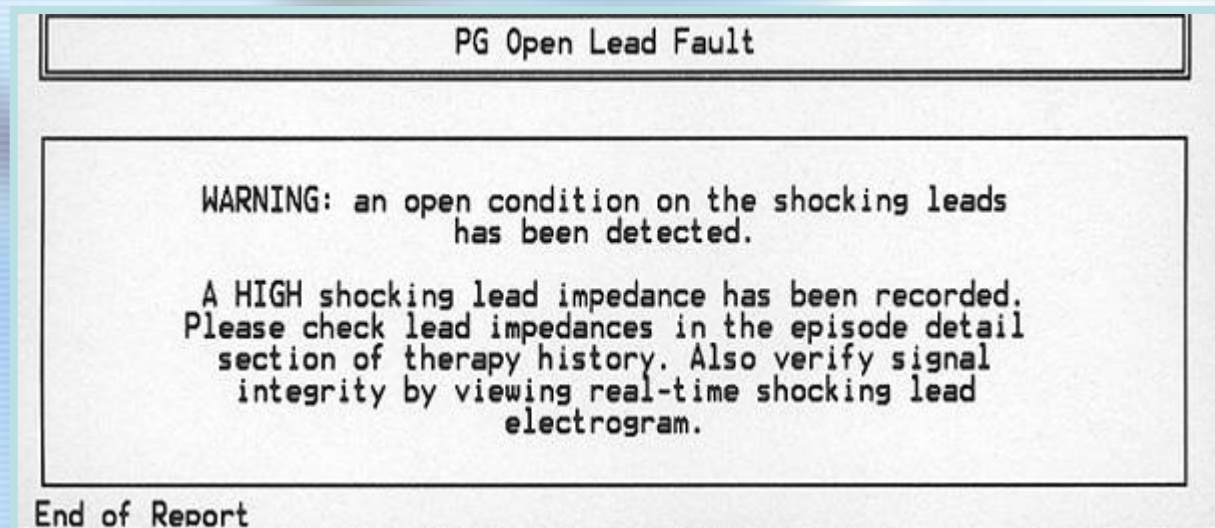
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Evaluate Shocking Lead Impedance



A "Fault" message and maximum or minimum impedance value indicates that all programmed energy was not delivered to patient

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Check Lead-to-Header Interface

- Defibrillating electrode ends fully inserted beyond connector block
- Setscrews tight



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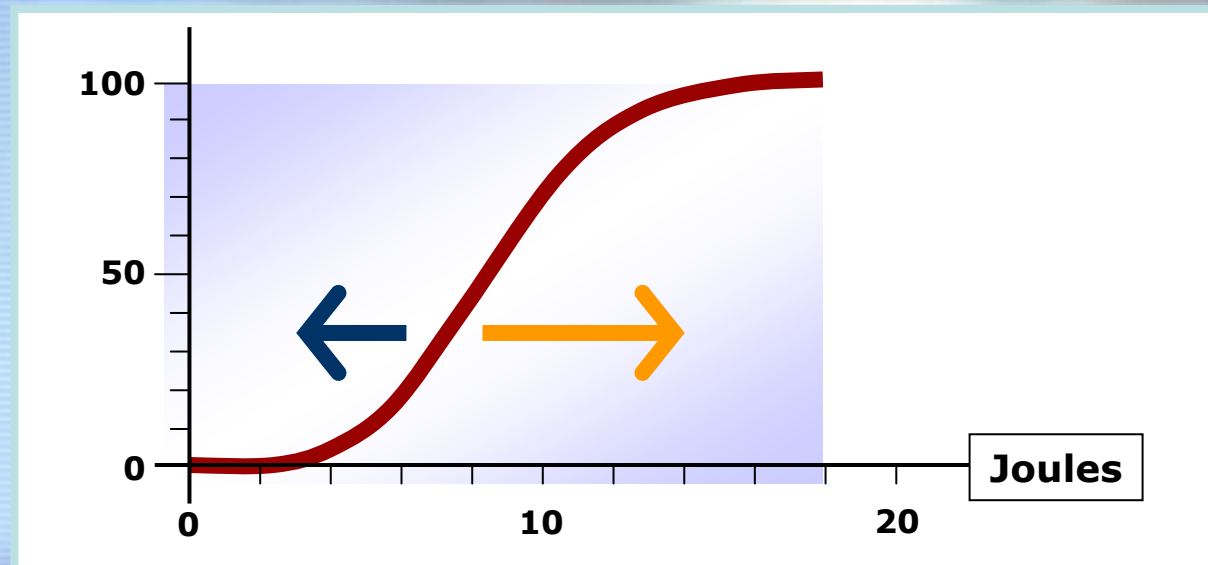
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Review Therapy History & Stored Electrograms

- Assess for new arrhythmia not previously observed or tested
- Evaluate effects of 1st programmed therapy:
 - Was there acceleration to VF after ATP &/or low energy cardioversion shocks

Assess Possible Reasons for Nonconversion

- Did programmed energy provided adequate safety margin, 10J?
 - Review DFT testing results
 - DFT may change with time



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Evaluate Changes in Patient that may Increase DFT

- Drug Regimen
- Disease Progression
- New Infarction

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Migrated SVC Spring Coil Lead



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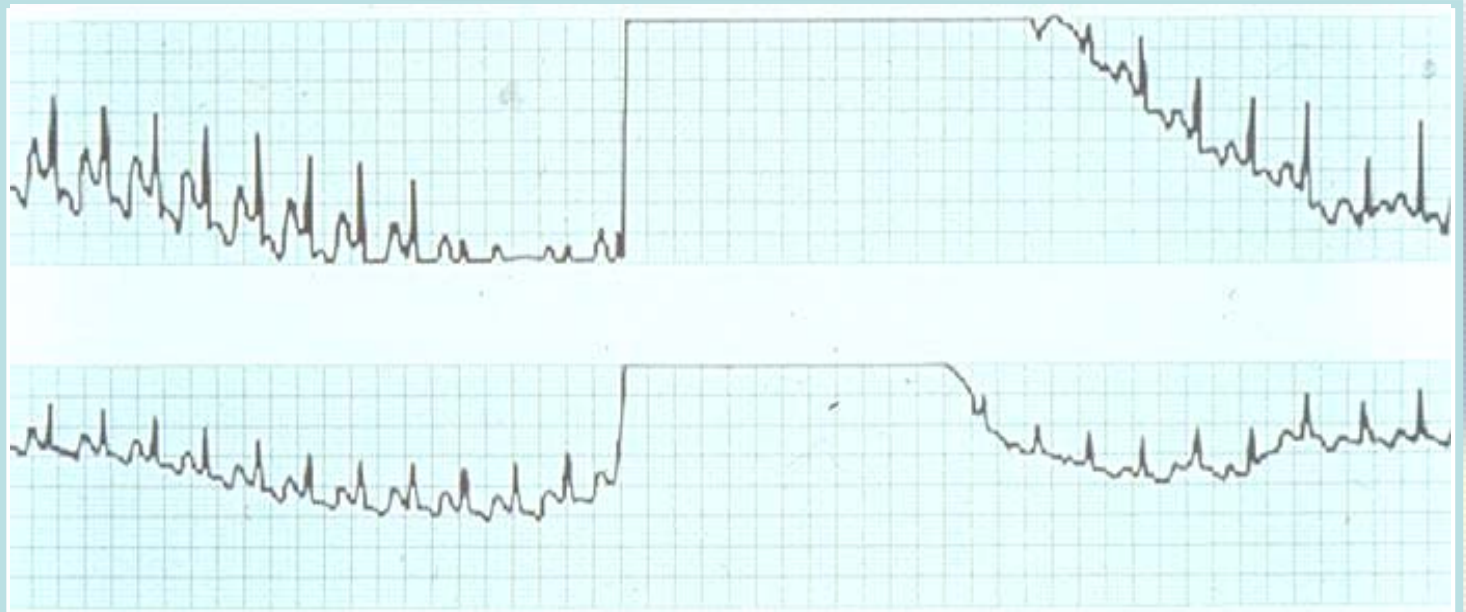
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Ventricular Rate Exceeds Rate Threshold



Shock delivered during atrial flutter with rapid ventricular conduction

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Determine Patient Status Prior to Therapy Delivery

- Activity Level
- Body Position



Review Therapy History

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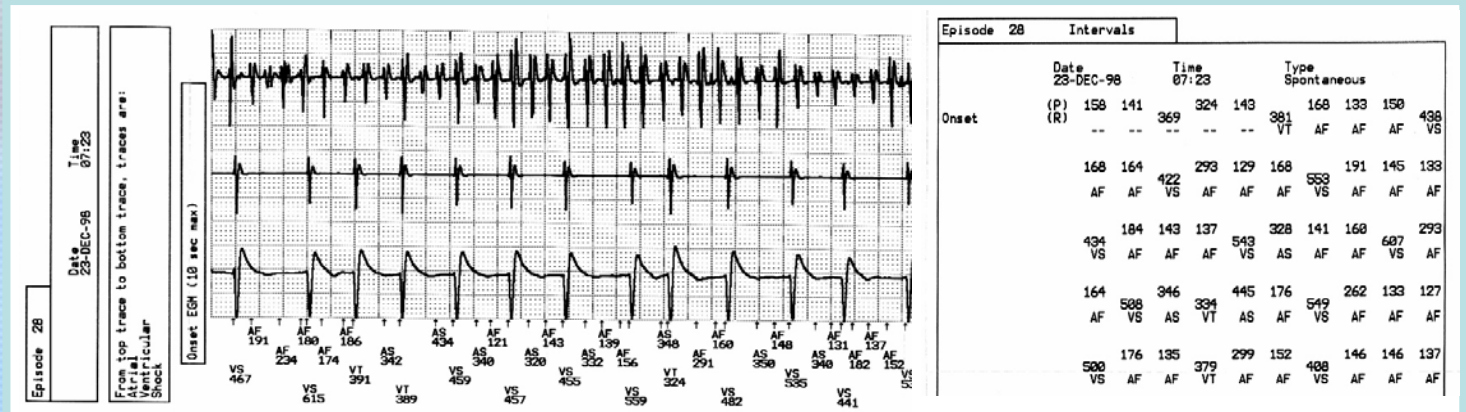
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- Criteria met
- R-R intervals, P-P intervals
- Nonsustained episodes
- Therapy delivered, i.e. acceleration from ATP to shocks

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Evaluate Stored Electrograms

- Onset & pre-therapy rhythms documented
- Annotated event markers (if available) indicate device categorization & response
- Atrial electrogram &/or shocking electrogram allows assessment of atrial activity
 - May help distinguish sinus tach & SVT (atrial fib/flutter) from VT

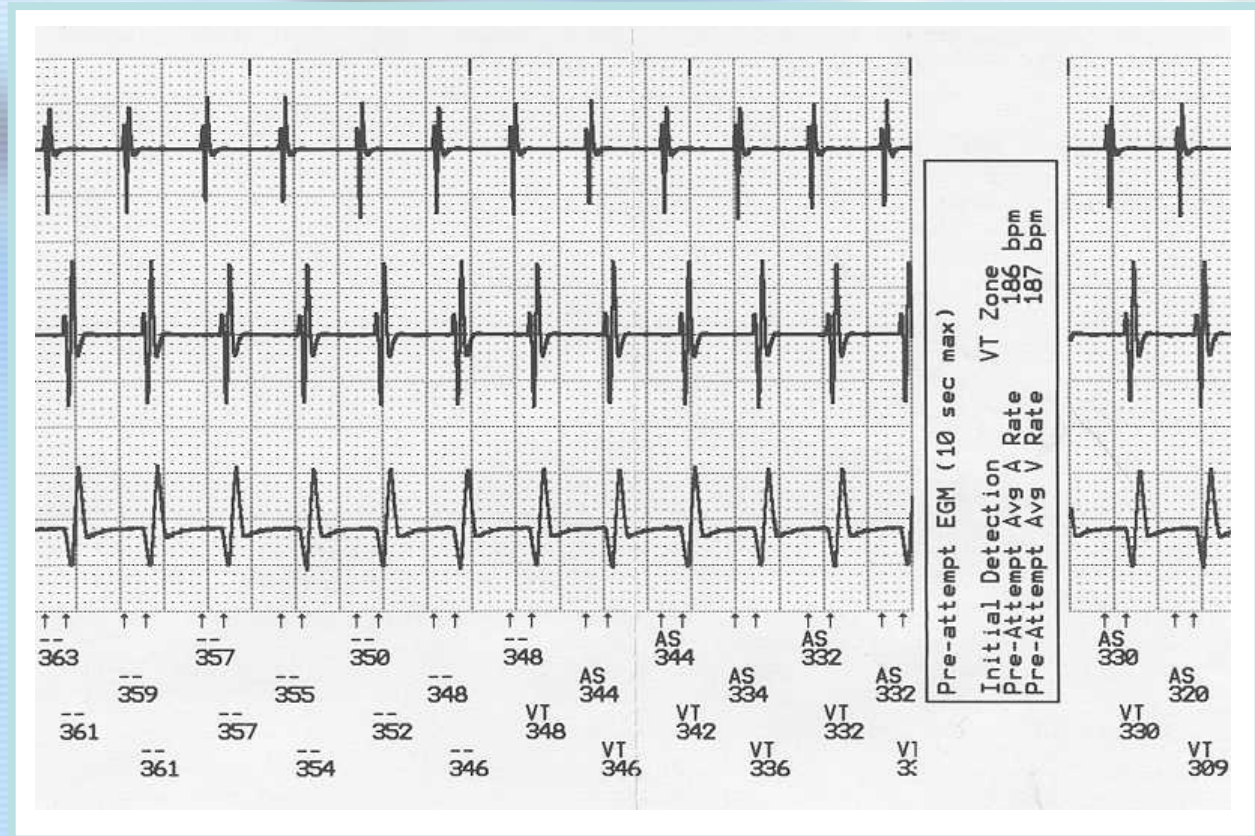
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Sinus Tachycardia Exceeds Rate Threshold

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Rhythm Needed to be able to Detect and Treat

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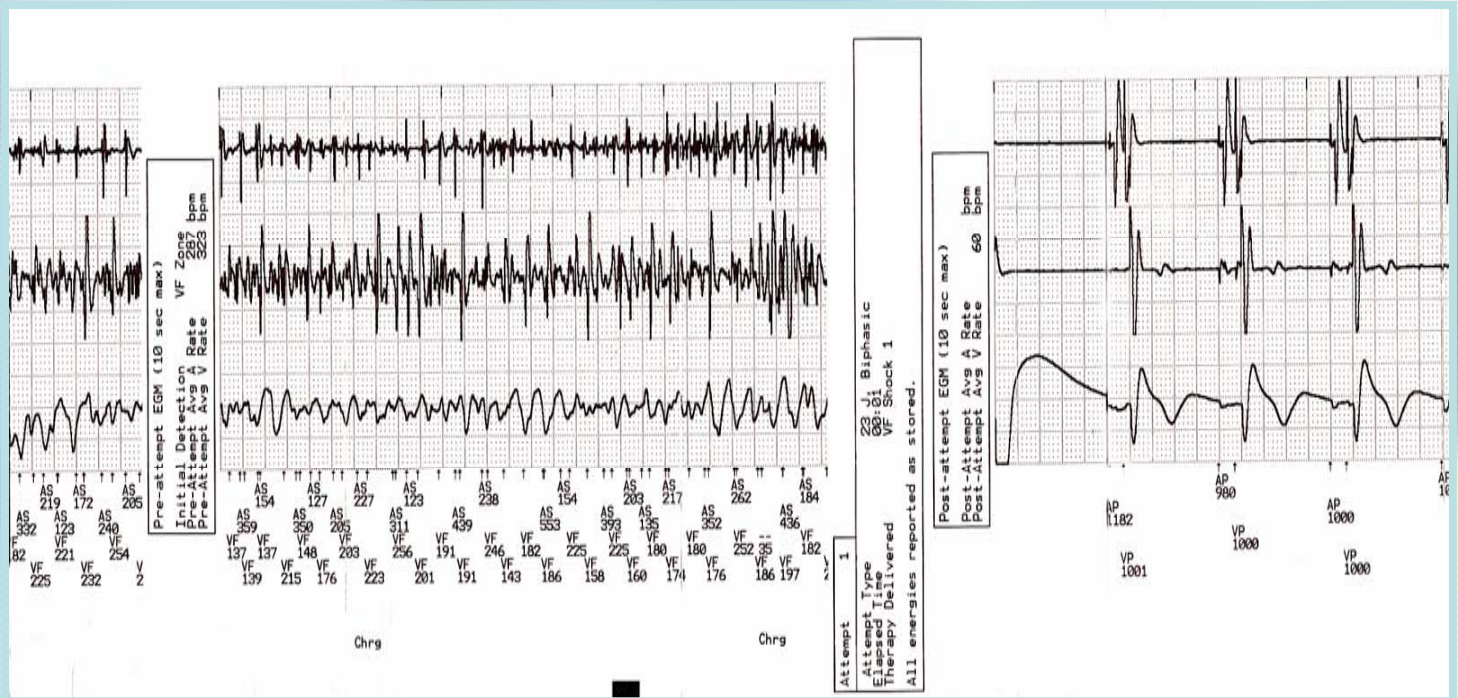
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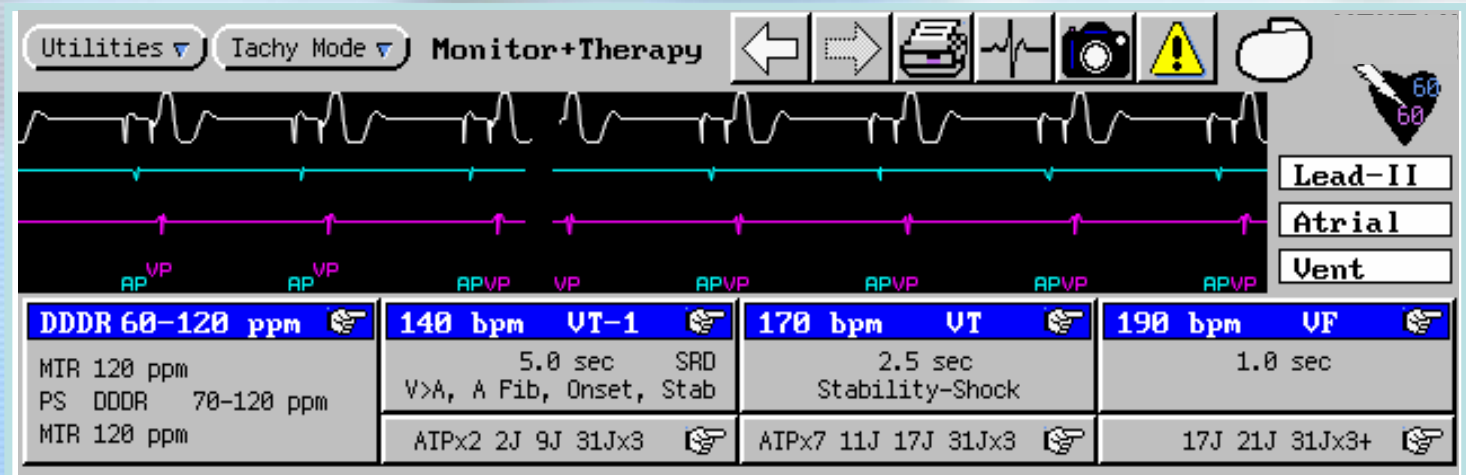
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Evaluate Rate Zone Boundaries



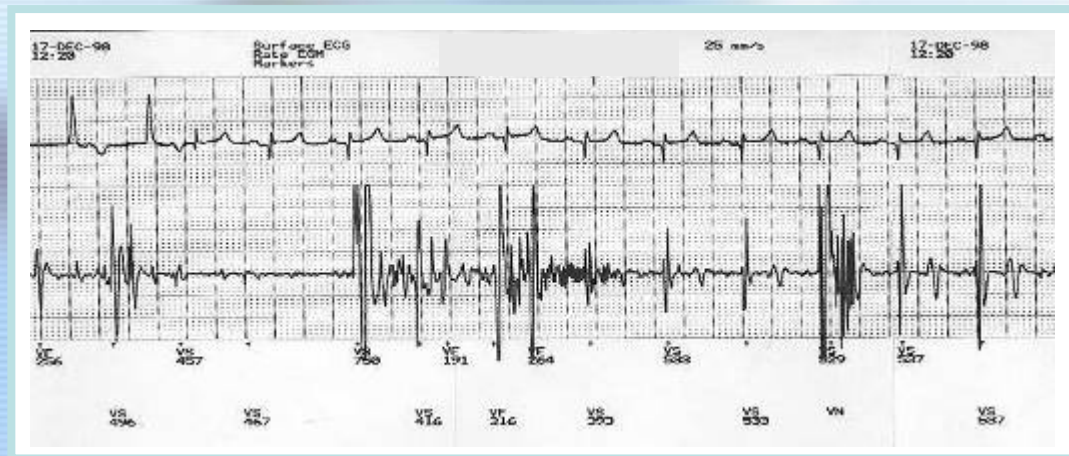
- Rate crossover may result in shocks instead of ATP
- Higher zone rate criterion should be a min of 10 bpm above VT rate of lower zone

Evaluate Beeping Tones for Appropriate Sensing

Magnet/Beeper/EGM Functions	
Enable Magnet Use	ON
Change Tachy Mode with Magnet	OFF
Beep During Capacitor Charge	OFF
Beep on Sensed Ventricular Events and Paced Ventricular Events	ON
Beep when ERI is Reached	ON

- Program on “beep on sensed events” for vigorous assessment while tachy status in “Monitor Only” mode
- Rhythmic, multiple tones may = oversensing of cardiac-related signal, i.e. pacing artifact & R-wave, P- & R-wave, etc.
- Magnet-induced tones for brief, at-rest assessment
- Erratic tones may = mechanical problem, noise, i.e. insulation break, lead connector interface problem, etc.

Evaluate Real-time Rate Sensing Electrogram



- Assess for presence and amplitude of other cardiac signals that may have been sensed, i.e. pacing artifact, P-wave, T-wave, etc.
- Inspect for “noise” artifact that may have been sensed

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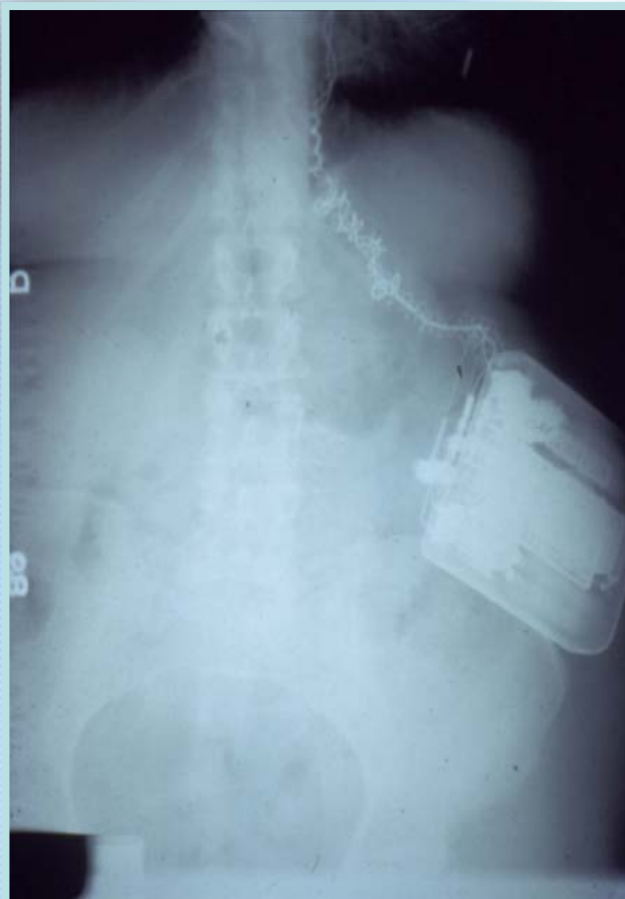
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Epicardial Lead System Clearly Compromised



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Indications

Guidant pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber systems are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm. Guidant pacing leads are intended for chronic pacing and sensing of the atrium and/or ventricle when used with a compatible pulse generator.

Contraindications

Guidant pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for MV detection; single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias, which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence or likelihood of competition between paced and intrinsic rhythms. Guidant pacing leads are also contraindicated in: patients with a hyper sensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate, patients with tricuspid valvular disease, patients with mechanical tricuspid heart valves, patients with an allergy to mannitol.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the pacing system. Such damage can result in injury to, or death of, the patient. Inappropriate sustained high-rate pacing occurred in the PULSAR MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced maximum pacing rate or MV PASSIVE. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4 → ON) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred. The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending or tension. This could cause structural weakness, conductor discontinuity or lead dislodgment.

Precautions

For information on precautions, read the following sections of the PG product labeling: clinical considerations, sterilization, storage and handling, lead evaluation and connection, implantation, programming and pacemaker operation, MV initialization, environmental and medical therapy hazards, home and occupational environments; and the lead product labeling: implant information and implantation. Advise patients to avoid lingering near anti-theft devices (electronic article surveillance [EAS]). Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. . It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects refer to the Physician's Desk Reference.

Potential Adverse Events

Potential adverse events from implantation of the Guidant pacing system include, but are not limited to, the following: allergic/physical reaction, death, erosion/migration, fibrillation or other arrhythmias, fracture/insulation break (lead or accessory), hematoma/seroma, inappropriate therapy, infection, lead displacement or dislodgment, pacing/sensing related, procedure related, random component failure.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.