CorePace – Module #2

Basic Pacing Concepts

Disclosures

This presentation is provided for general educational purposes only and should not be considered the exclusive source for this type of information. At all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in a particular situation.

The device functionality and programming described in this module are based on Medtronic products and can be referenced in the device manuals.

Updated: April 2012

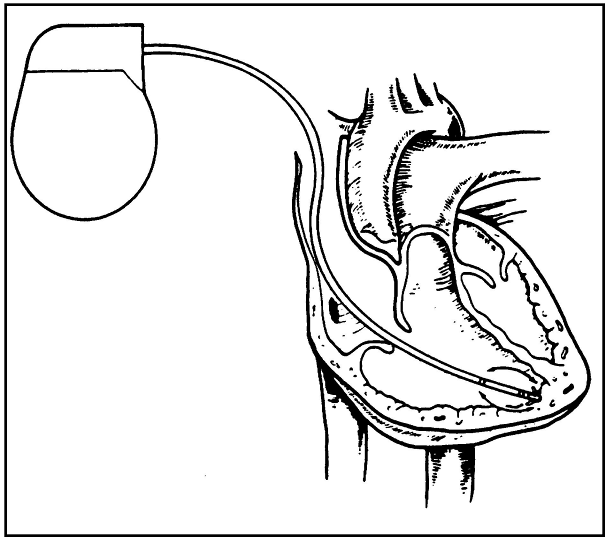
Objectives

- Explain the different types of pacemakers and the NBG Code
- Identify the components of a pacemaker circuit
- Describe the relationship between voltage, current, and resistance
- Describe the clinical significance of alterations in voltage, current, and resistance
- Recognize low and high impedance conditions and possible causes
- Identify a capture threshold and calculate safety margins
- Understand sensing and sensitivity in a pacemaker

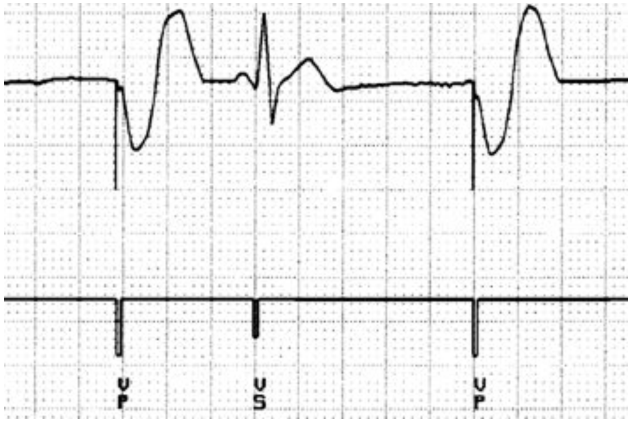
TYPES OF PACEMAKERS

Single Chamber System

- One lead
  - Atrium
  - Ventricle (most common)
- May be used for patients in chronic AF (VVI pacemaker) or patients with sinus node dysfunction and no history of AV block (AAI pacemaker)



VVI Pacemaker

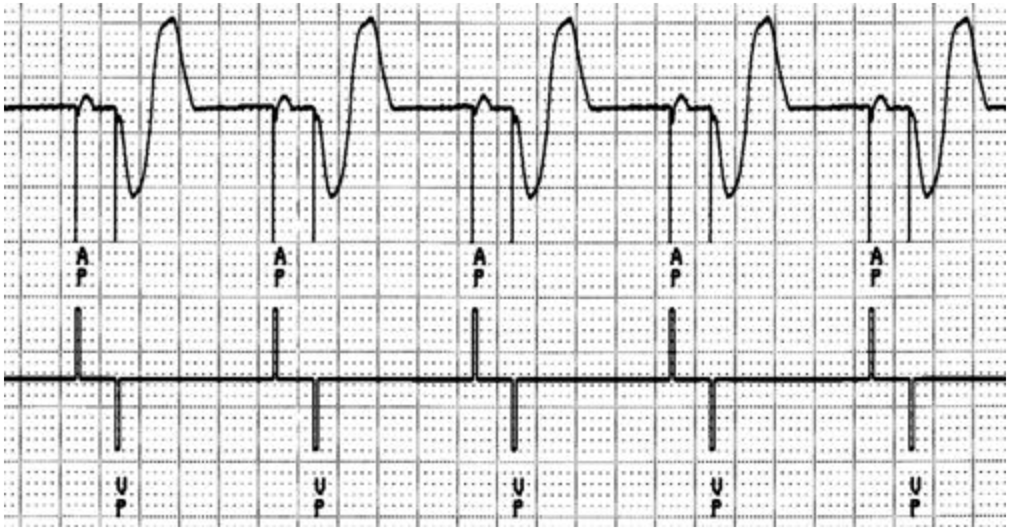


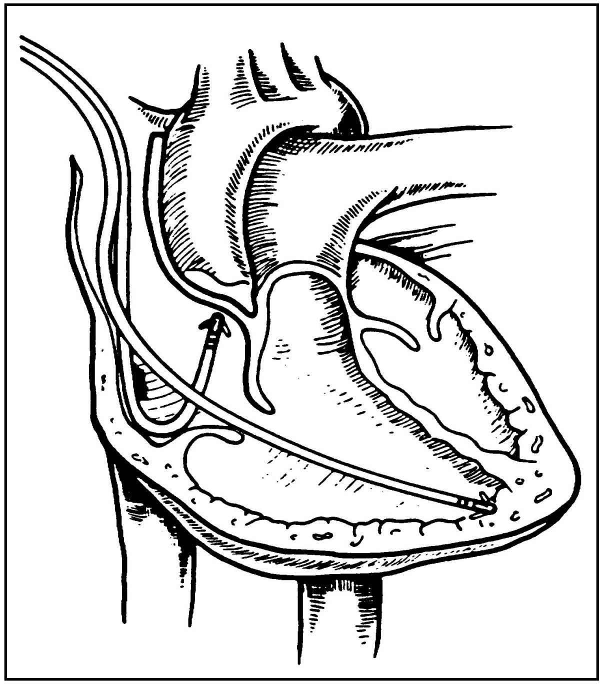
AAI Pacemaker

Dual Chamber System

- Two leads
  - One lead implanted in the atrium
  - One lead implanted in the ventricle
- Provides AV synchrony and pacing support in both atrium and ventricle if needed

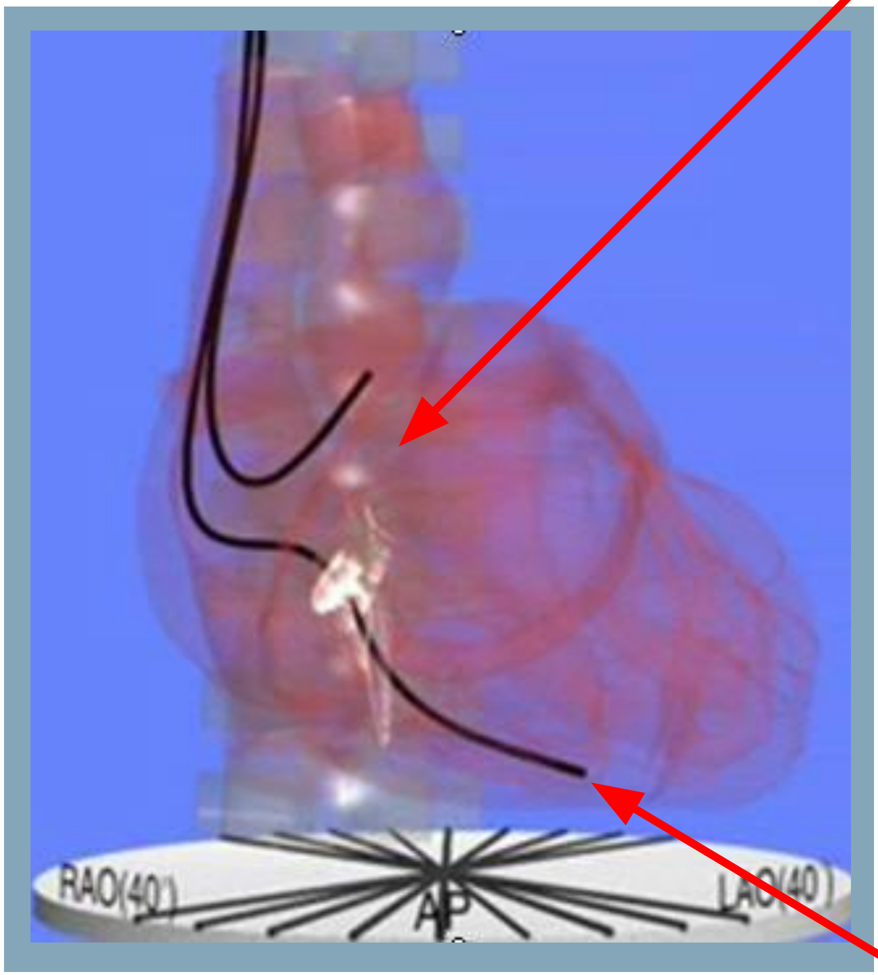
DDD Pacemaker

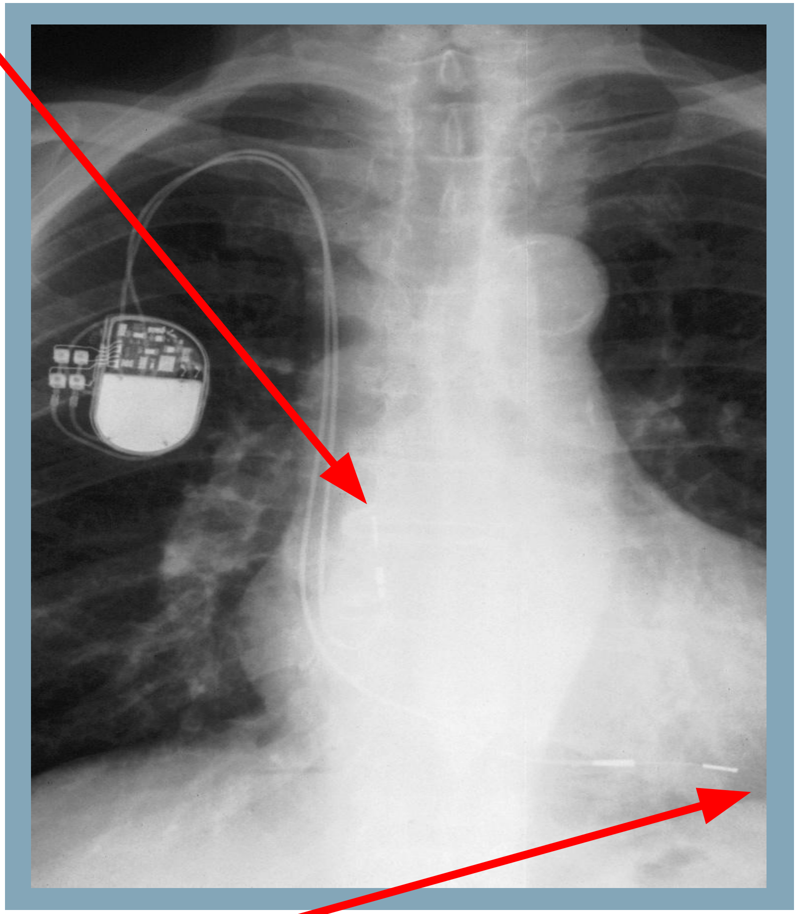




Dual Chamber Pacemaker

RA Lead in Appendage



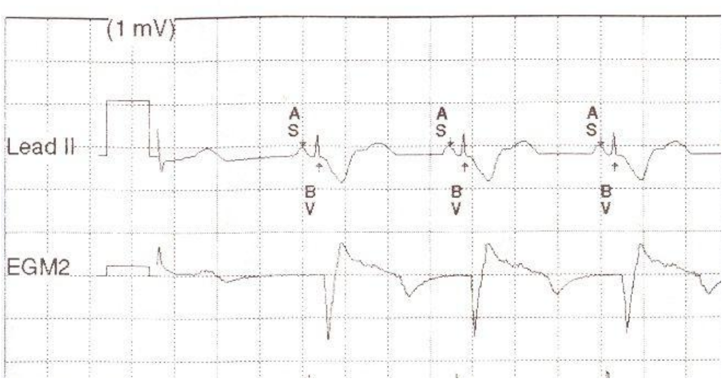


RV Lead at the Apex

Triple Chamber System

- Three Leads:
  - Right Atrium
  - Right Ventricle
  - Left Ventricle (via the Coronary Sinus vein)
- Most commonly called a Bi-Ventricular Pacemaker but also called Cardiac Resynchronization Therapy (CRT–P)
- Paces both ventricles together to “resynchronize” the beat

DDD BiV Pacemaker



NBG Code – The Usual Pacing Modes

I	II	III	IV	V
Chamber(s) Paced	Chamber(s) Sensed	Response to Sensing	Rate Modulatio n	Multisite Pacing
O = None **A** = Atrium **V** = Ventricle **D** = Dual (A + V) **S** = Single (A or V)	**O** = None **A** = Atrium **V** = Ventricle **D** = Dual (A + V) **S** = Single (A or V)	**O** = None **T** = Triggered **I** = Inhibited **D** = Dual (T + I)	**O** = None **R** = Rate modulation	**O** = None **A** = Atrium **V** = Ventricle **D** = Dual (A + V)

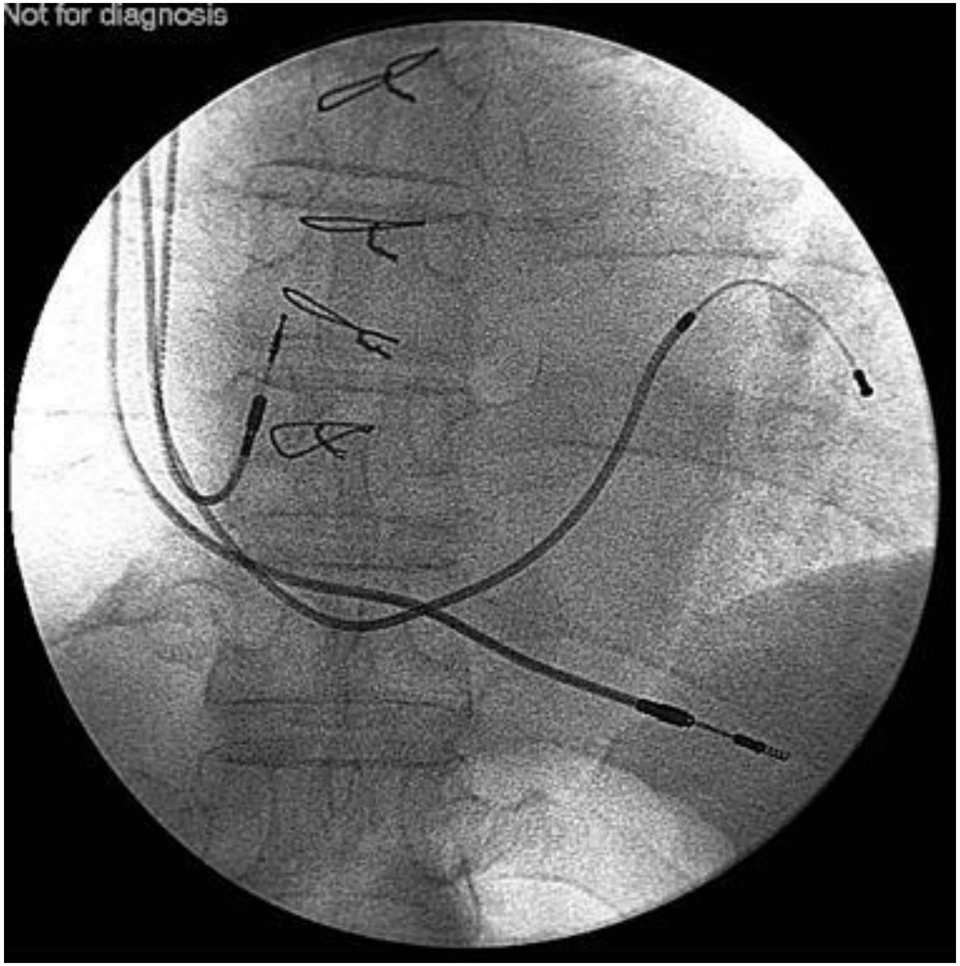
Examples of pacing modes which are typically programmed:

DDD **VVI** **DDIR**

DDDR **VVIR** **AAIR**

Knowledge Checkpoint

What type of pacemaker is this?



Knowledge Checkpoint

What does VVIR mode mean?

Key Learning Points

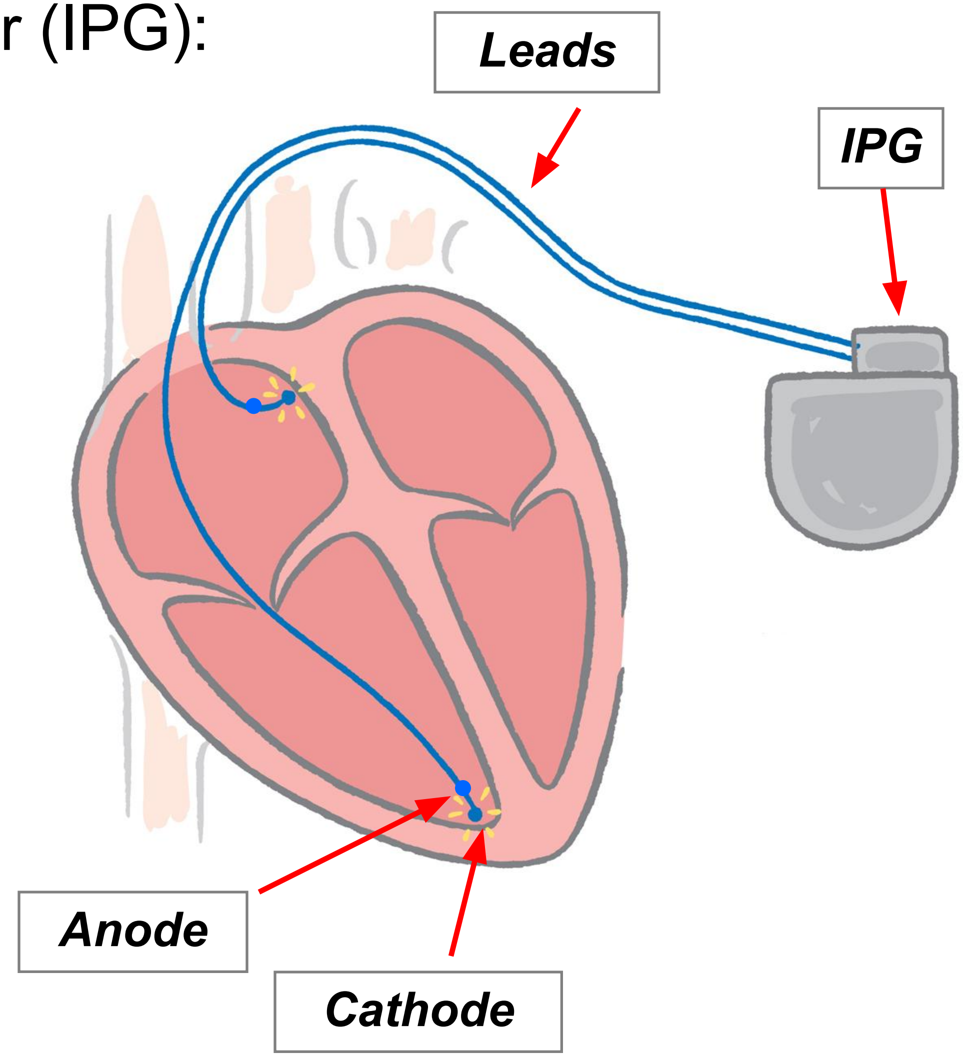
- There are three types of pacemakers
  - Important to identify which one the patient has and why

- The mode explains how the pacemaker should work
  - Very important to understanding the basic function of the device

COMPONENTS OF THE PACEMAKER SYSTEM

Implantable Pacemaker Circuit

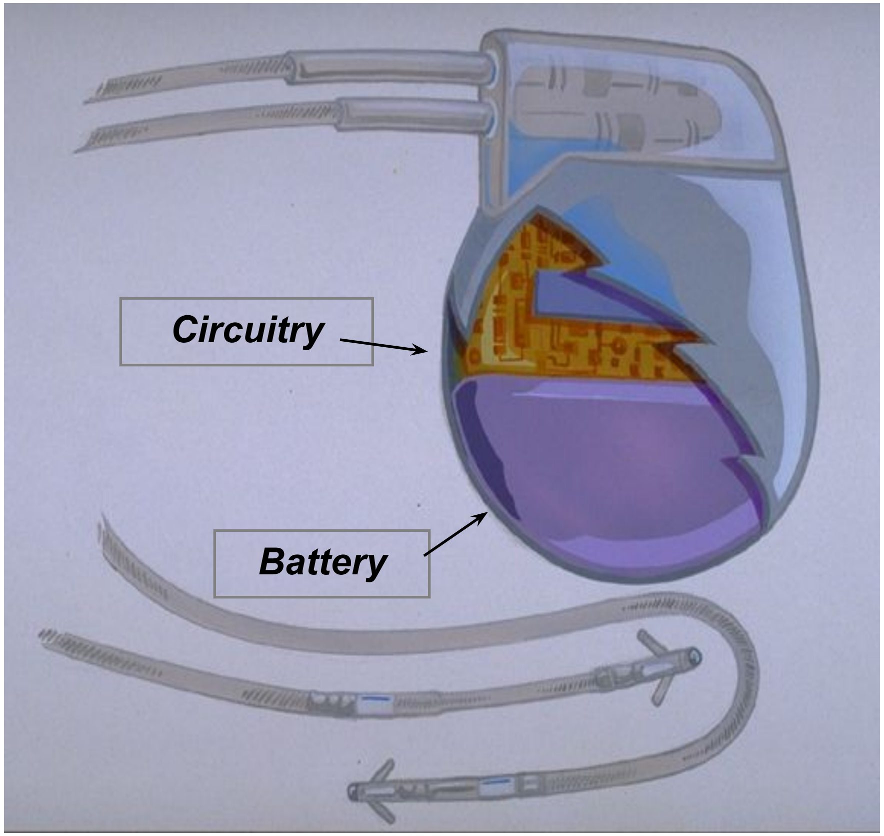
- Implantable pulse generator (IPG):
  - Battery
  - Circuitry
  - Connector(s)
- Leads or wires
  - Cathode (negative electrode)
  - Anode (positive electrode)
- Body tissue



The Pulse Generator

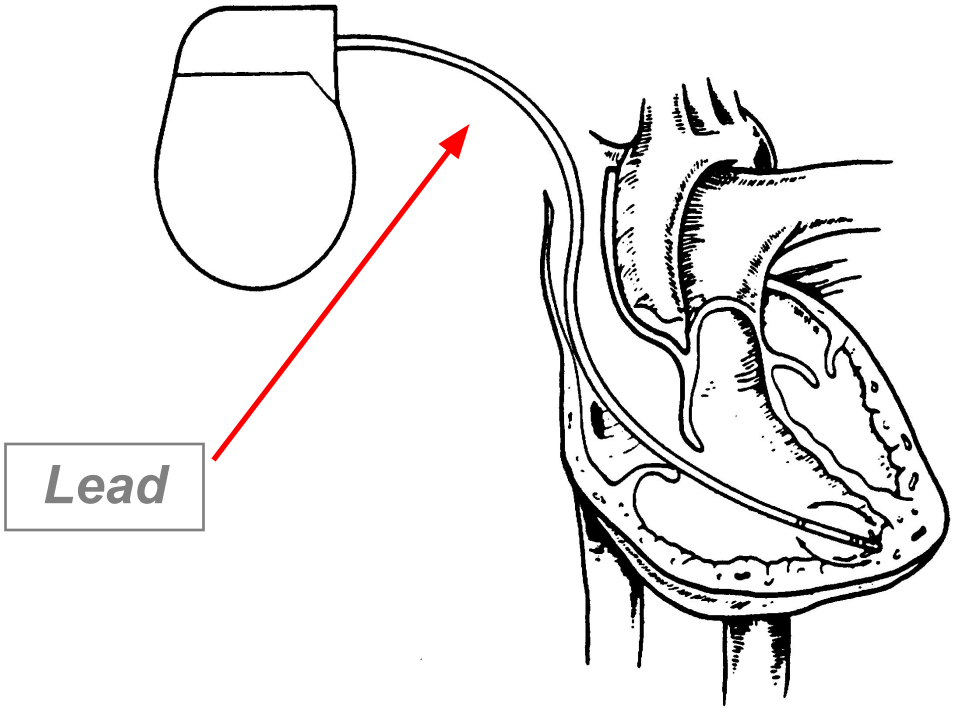
- Lithium-Iiodine Battery
  - 2.8 V BOL

- Longevity
  - Dependent on impedance and output
  - Ranges from 6-12 years



Leads are Insulated Wires

- Deliver electrical impulses from the pulse generator to the heart
- Sense cardiac depolarization

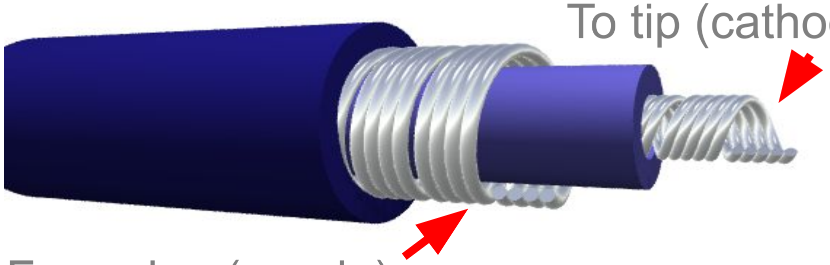


Lead Polarity

- Unipolar leads
  - May have a smaller diameter lead body than bipolar leads
  - May exhibit larger pacing artifacts on the surface ECG
  - May cause pectoral muscle stimulation

Unipolar lead

- Bipolar leads
  - Usually less susceptible to oversensing of non-cardiac signals (i.e., myopotentials, EMI, etc.)



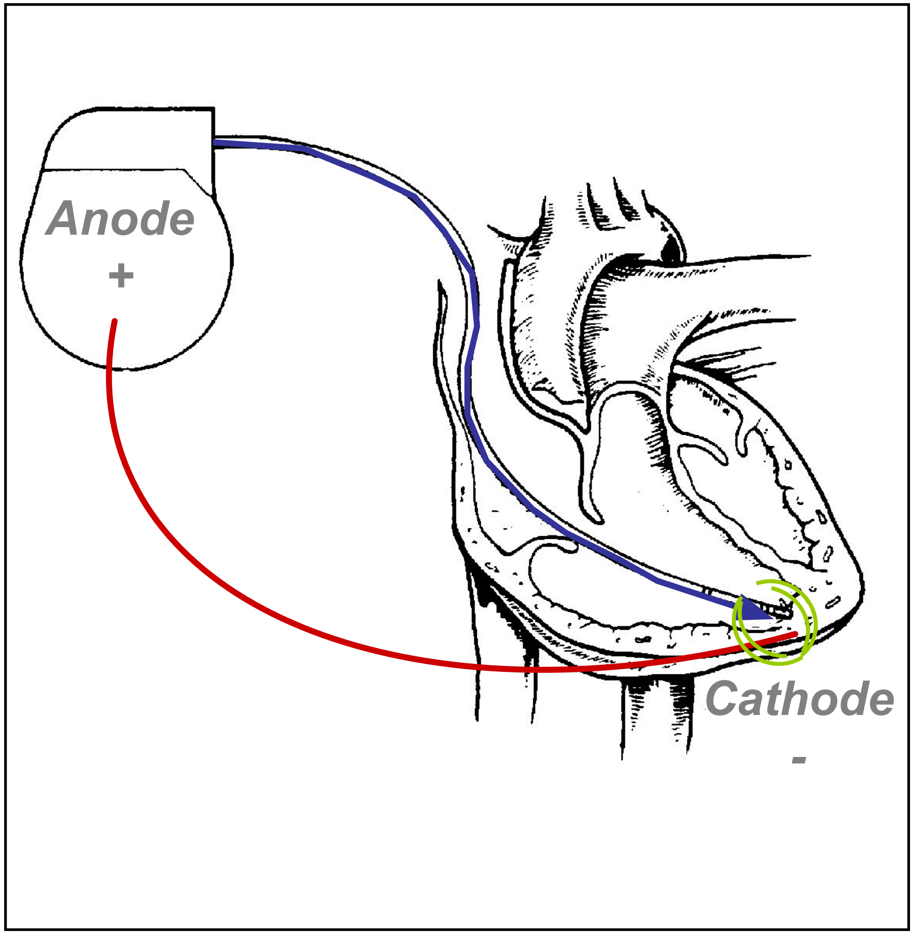
Bipolar coaxial lead

Al-Ahmad, Amin, et. al. (2010). **Pacemakers and Implantable Cardioverter Defibrillators: An Expert's Manual** Minneapolis: Cardiotext Publishing. (pg. 20-21).

Unipolar Pacing System

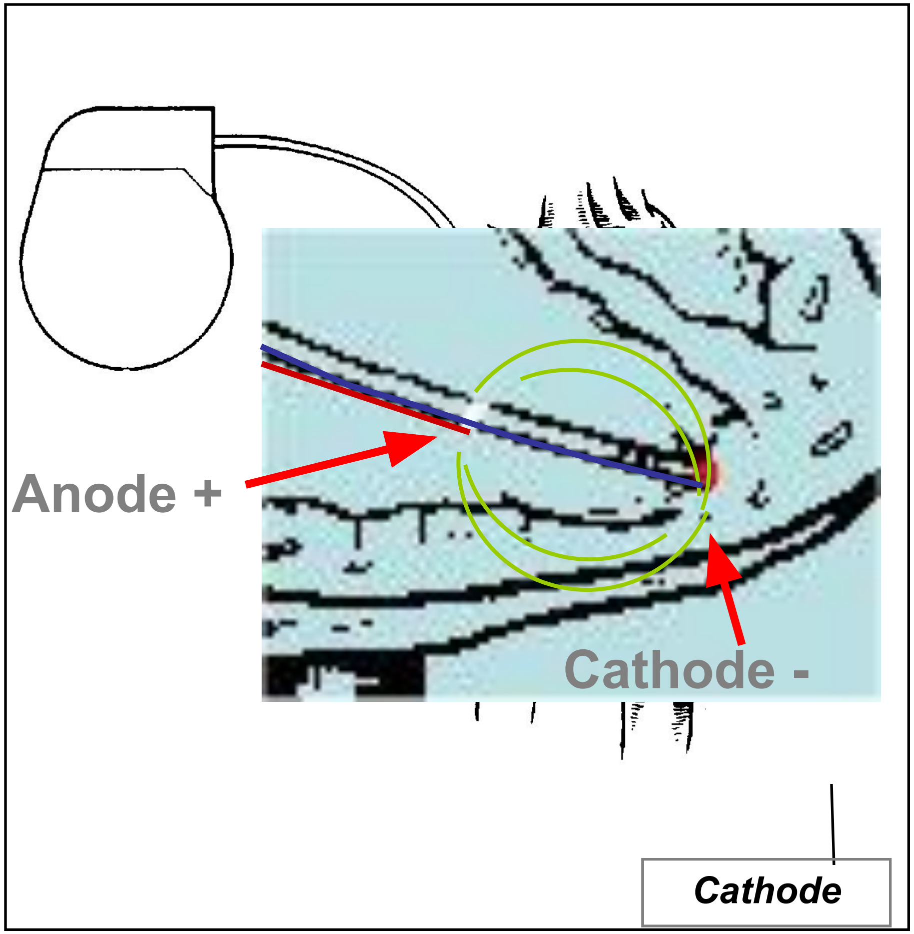
- The lead has only one electrode (the cathode) at the tip
- The pacemaker can is the anode
- When pacing, the impulse:
  - Flows through the tip electrode (cathode)
  - Stimulates the heart
  - Returns through body fluid and tissue to the IPG can (anode)

- Why might this be important to know during a procedure?



Bipolar Pacing System

- The lead has both an anode and cathode
- The pacing impulse:
  - Flows through the tip electrode located at the end of the lead wire
  - Stimulates the heart
  - Returns to the ring electrode, the anode, above the lead tip



Transvenous Leads

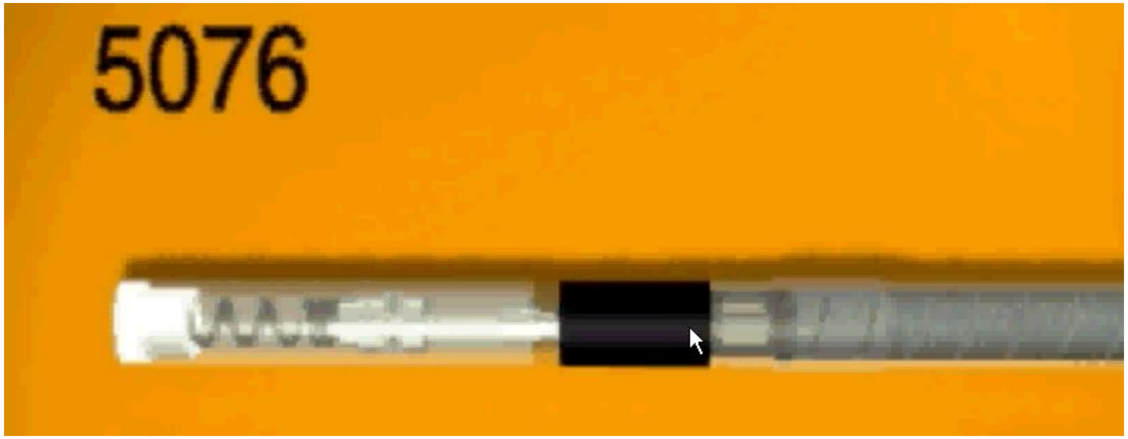
Passive fixation (tined)

The tines become lodged in the trabeculae of the apex or the pectinate of the appendage which are fibrous meshworks of heart tissue

Active fixation (screw-in)

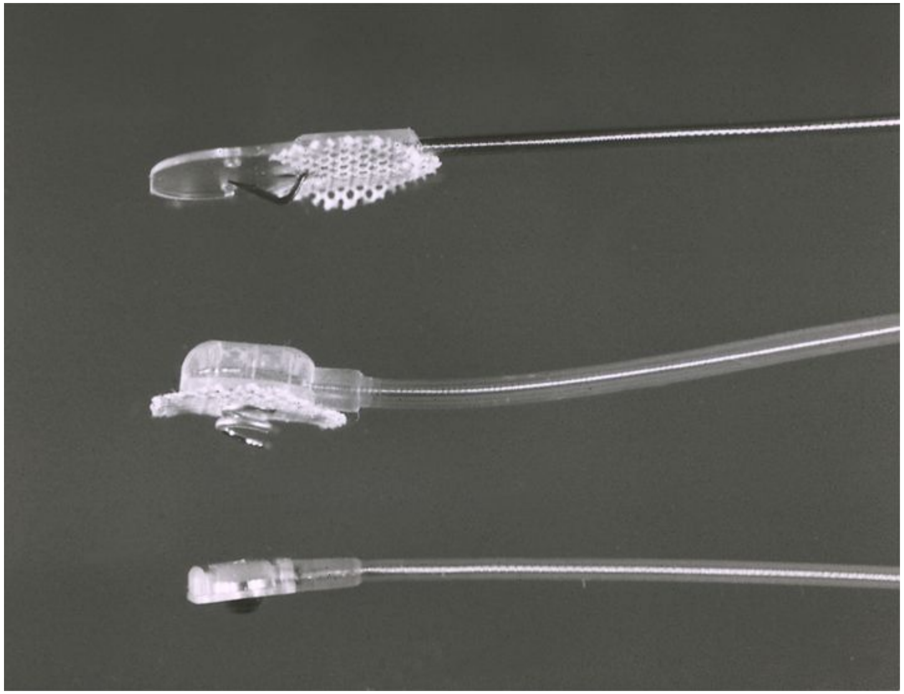
The helix, or screw, extends into the endocardial tissue

- Allows for lead positioning anywhere in the heart's chamber
- The helix is extended using an included tool



Epicardial Leads

- Leads applied directly to the surface of the heart
  - Utilized in pediatric patients and patients contraindicated for transvenous leads
  - Fixation mechanisms include:
    - Epicardial stab-in
    - Myocardial screw-in
    - Suture-on
  - Applied via sternotomy, thoroscopy, or limited thoracotomy



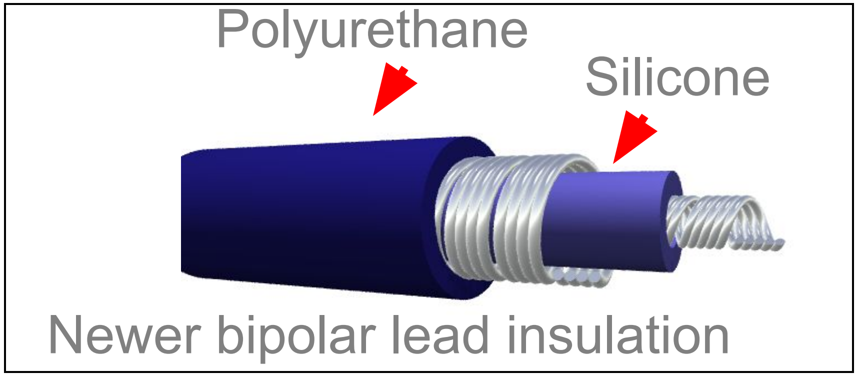
Lead Insulators

Silicone insulated leads

- Inert
- Biocompatible
- Biostable
- Repairable with medical adhesive
- Historically very reliable

Polyurethane insulated leads

- Biocompatible
- High tear strength
- Low friction coefficient
- Smaller lead diameter

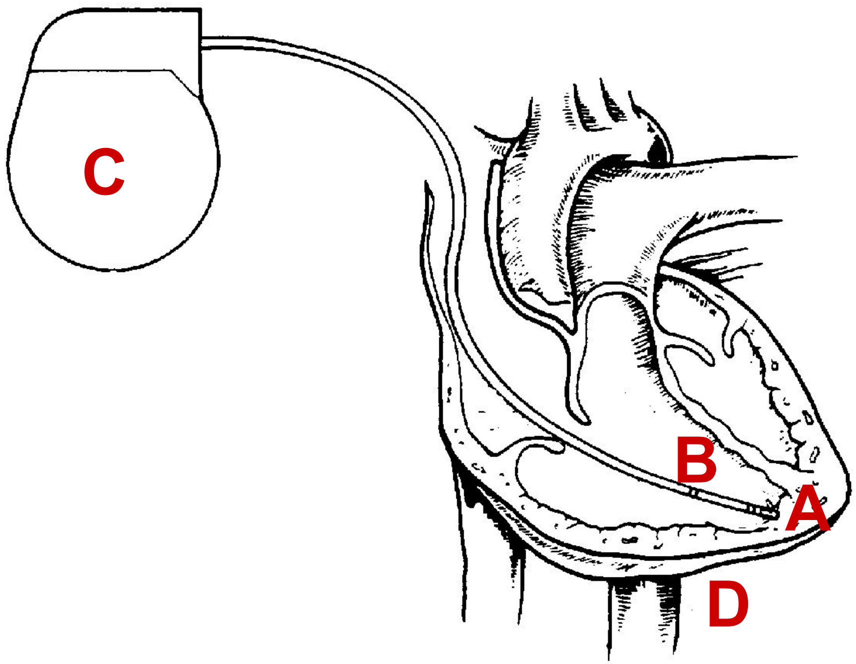


Hayes, David L., et. al. (2008). **Cardiac pacing, defibrillation and resynchronization: a clinical approach.** New Jersey: Wiley-Blackwell Publishing. (pg. 127).

Knowledge Checkpoint

Where is the anode located in bipolar pacing?

A. Tip Electrode
B. Ring Electrode
C. Device
D. Body Tissue



Key Learning Points

- The pacemaker circuit consists of the leads, device, and tissue
- Modern leads are usually bipolar, endocardial, and active fixation but all types of leads are available
  - Important to know what type of lead is implanted because it can be helpful for diagnosing a problem and determining solutions

ELECTRICAL CONCEPTS IN PACEMAKERS

Voltage

- Voltage is the force, or “push,” that causes electrons to move through a circuit
- In a pacing system, voltage is:
  - Measured in volts (V)
  - Represented by the letter “V”
  - Provided by the pacemaker battery
  - Often referred to as amplitude or pulse amplitude

Note: The terms “amplitude” and “voltage” are often used interchangeably in pacing.

Initial Interrogation Report

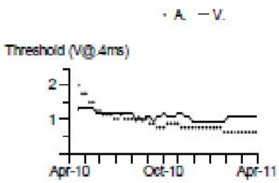
DEMONSTRATION ONLY - Initial Interrogation Report

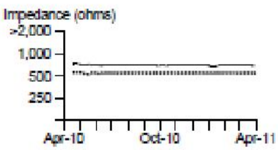
Pacemaker Model: Medtronic Adapta ADDR01 Serial Number: PWB002560 Date of Visit: 04/18/11

Patient Name:	ID:	Physician:

History: Sinus Node Dysfunction + AT/AF, Normal AV Conduction, NYHA Class I

Pacemaker Status (Implanted: 04/29/10)





Battery Status

Estimated remaining longevity: 9.5 years, 7.5 - 11 years
Based on Past History
Voltage/Impedance 2.77 V / 103 ohms

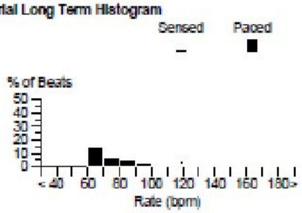
Lead Summary	Atrial	Ventricular
Measured Threshold	0.625 V at 0.40 ms	1.000 V at 0.40 ms
Date Measured	04/17/11	04/17/11
Programmed Output	1.500 V / 0.40 ms	2.000 V / 0.40 ms
Capture	Adaptive	Adaptive
Measured P / R Wave	0.7 to 2.8 mV	16.0 to 22.4 mV
Programmed Sensitivity	0.50 mV	5.60 mV
Measured Impedance	547 ohms	667 ohms
Lead Status	OK	OK
Lead Model Implanted	5076	5076

Parameter Summary

Mode	AAIR<=>DDDR	Lower Rate	60 ppm	Paced AV	150 ms
Mode Switch	On	Upper Tracking Rate	130 ppm	Sensed AV	120 ms
Detection Rate	175 bpm	Upper Sensor Rate	130 ppm		

Clinical Status: 10/09/10 to 04/18/11

Atrial Long Term Histogram



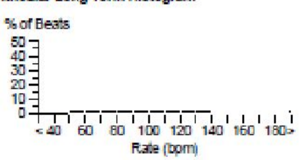
Mode Switches: 251 (Percent of Time: 2.1%)
Atrial High Rate Episodes: 204
Episode Trigger: Mode Switch > 30 sec

Date/Time	Duration hh:mm:ss		Rate (bpm) Max A	Max V
03/05/11 6:48 AM	:16:28	First	400	90
04/12/11 11:23 AM	6:11:38	Longest	>400	87
04/15/11 8:32 AM	3:06:40	Fastest	>400	98
04/18/11 10:09 AM	:31:07	Last	400	93

Ventricular High Rate Episodes: 1

04/12/11 2:16 PM	:11	Longest...	87	265

Ventricular Long Term Histogram



Pacing (% of total):	
AS - VS	72.1%
AS - VP	2.3%
AP - VS	24.7%
AP - VP	0.8%
MVP	On

Event Counters	
PVC singles	2,745
PVC runs	92
PAC runs	0

Lead Summary	Atrial	Ventricular
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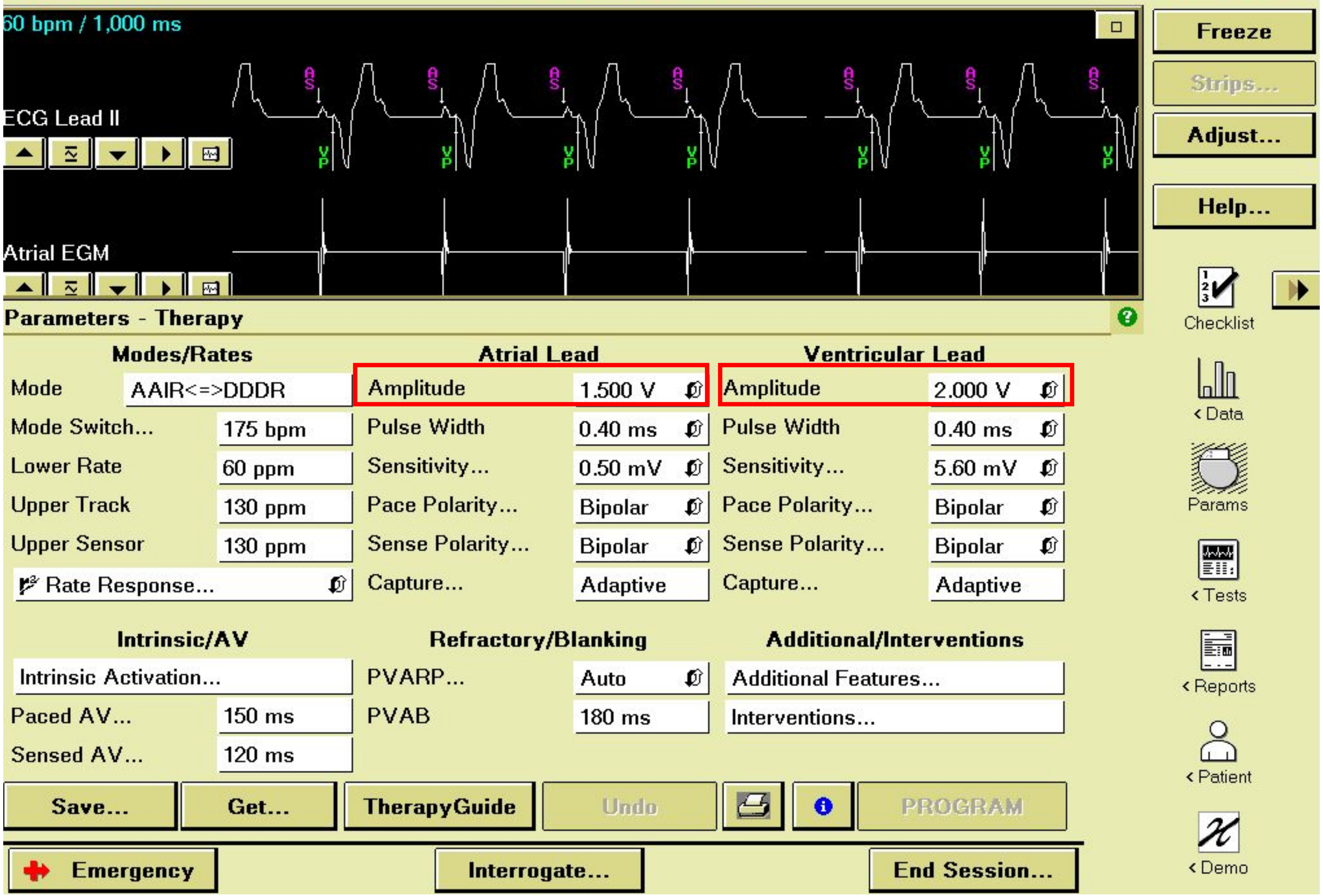
Lead Status	OK	OK

Note: All clinic, physician, and patient names and data in this document are fictitious

Voltage

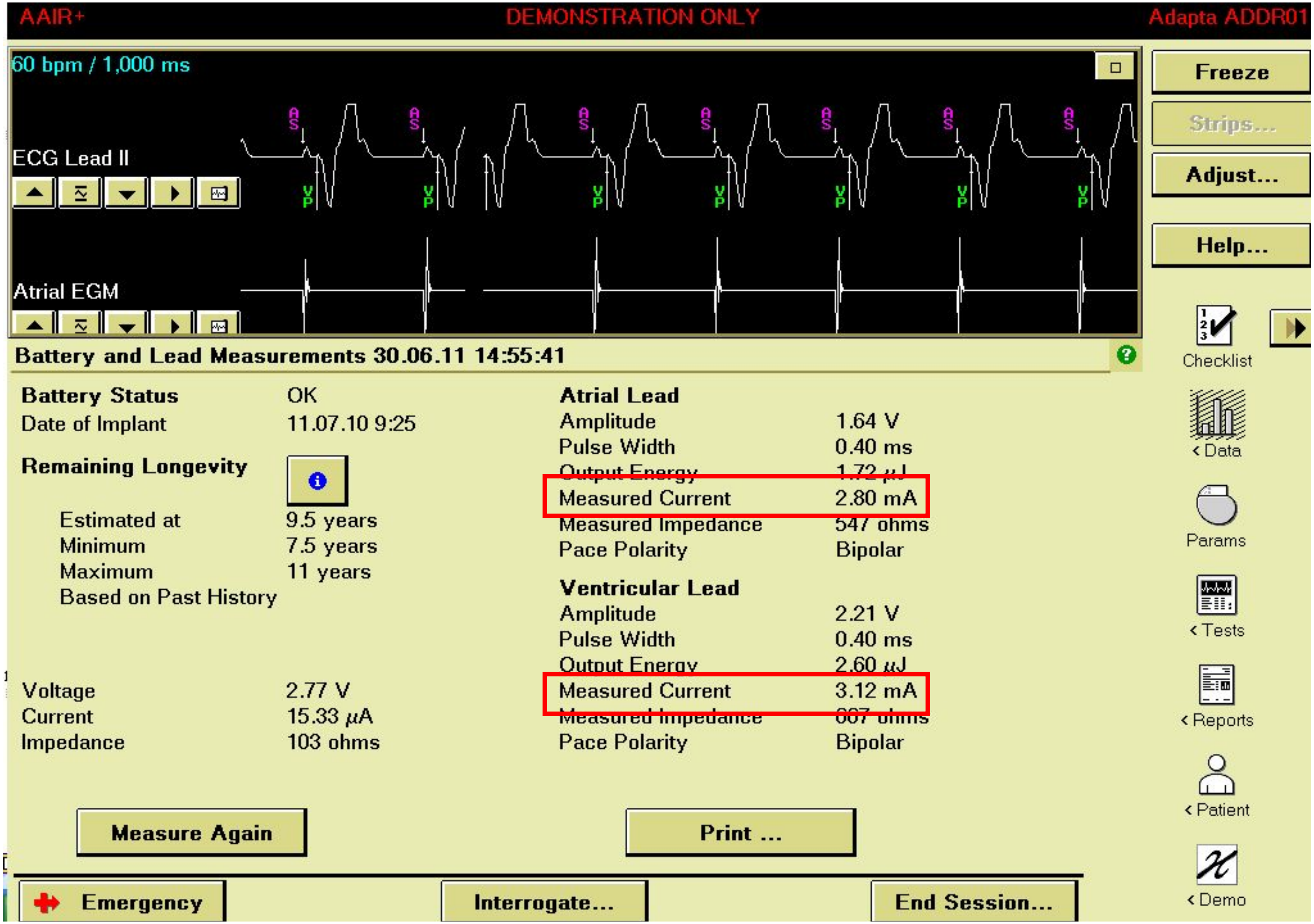

60 bpm / 1,000 ms
ECG Lead II
Atrial EGM
Freeze
Strips...
Adjust...
Help...
Checklist
< Data
Params
< Tests
< Reports
< Patient
< Demo
Parameters - Therapy
Modes/Rates
Mode
AAIR<=>DDDR
Mode Switch...
175 bpm
Lower Rate
60 ppm
Upper Track
130 ppm
Upper Sensor
130 ppm
Rate Response...
Atrial Lead
Amplitude
1.500 V
Pulse Width
0.40 ms
Sensitivity...
0.50 mV
Pace Polarity...
Bipolar
Sense Polarity...
Bipolar
Capture...
Adaptive
Ventricular Lead
Amplitude
2.000 V
Pulse Width
0.40 ms
Sensitivity...
5.60 mV
Pace Polarity...
Bipolar
Sense Polarity...
Bipolar
Capture...
Adaptive
Intrinsic/AV
Intrinsic Activation...
Paced AV...
150 ms
Sensed AV...
120 ms
Refractory/Blanking
PVARP...
Auto
PVAB
180 ms
Additional/Interventions
Additional Features...
Interventions...
Save...
Get...
TherapyGuide
Undo
PROGRAM
Emergency
Interrogate...
End Session...

Current

- The flow of electrons through a completed circuit
- In a pacing system, current is:
  - Measured in milliamps (mA)
  - Represented by the letter “I”
  - Determined by the amount of electrons that move through a circuit

Note: One ampere is a unit of electrical current produced by 1 volt acting through a resistance of 1 ohm. 1 Ampere = 1000 milliamps

Current



AAIR+
DEMONSTRATION ONLY
Adapta ADDR01
60 bpm / 1,000 ms
ECG Lead II
Atrial EGM
Freeze
Strips...
Adjust...
Help...
Checklist
< Data
Params
< Tests
< Reports
< Patient
< Demo
Battery and Lead Measurements 30.06.11 14:55:41
Battery Status OK
Date of Implant 11.07.10 9:25
Remaining Longevity
Estimated at 9.5 years
Minimum 7.5 years
Maximum 11 years
Based on Past History
Voltage 2.77 V
Current 15.33 µA
Impedance 103 ohms
Atrial Lead
Amplitude 1.64 V
Pulse Width 0.40 ms
Output Energy 1.72 µJ
Measured Current 2.80 mA
Measured Impedance 547 ohms
Pace Polarity Bipolar
Ventricular Lead
Amplitude 2.21 V
Pulse Width 0.40 ms
Output Energy 2.60 µJ
Measured Current 3.12 mA
Measured Impedance
Pace Polarity Bipolar
Measure Again
Print ...
Emergency
Interrogate...
End Session...

Impedance

- The opposition to current flow
- In a pacing system, impedance is:
  - Measured in ohms (Ω)
  - Represented by the letter "R"
  - The sum of all resistances to the flow of current
    - Lead conductor resistance
    - The resistance to current flow from the electrode to the myocardium
    - Polarization impedance (the accumulation of charges of opposite polarity in the myocardium at the electrode-tissue interface)

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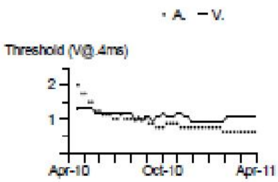

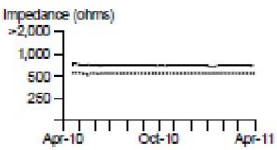

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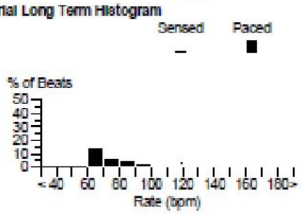

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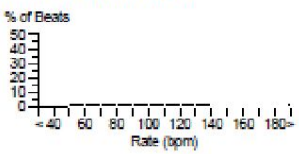
Ventricular Long Term Histogram



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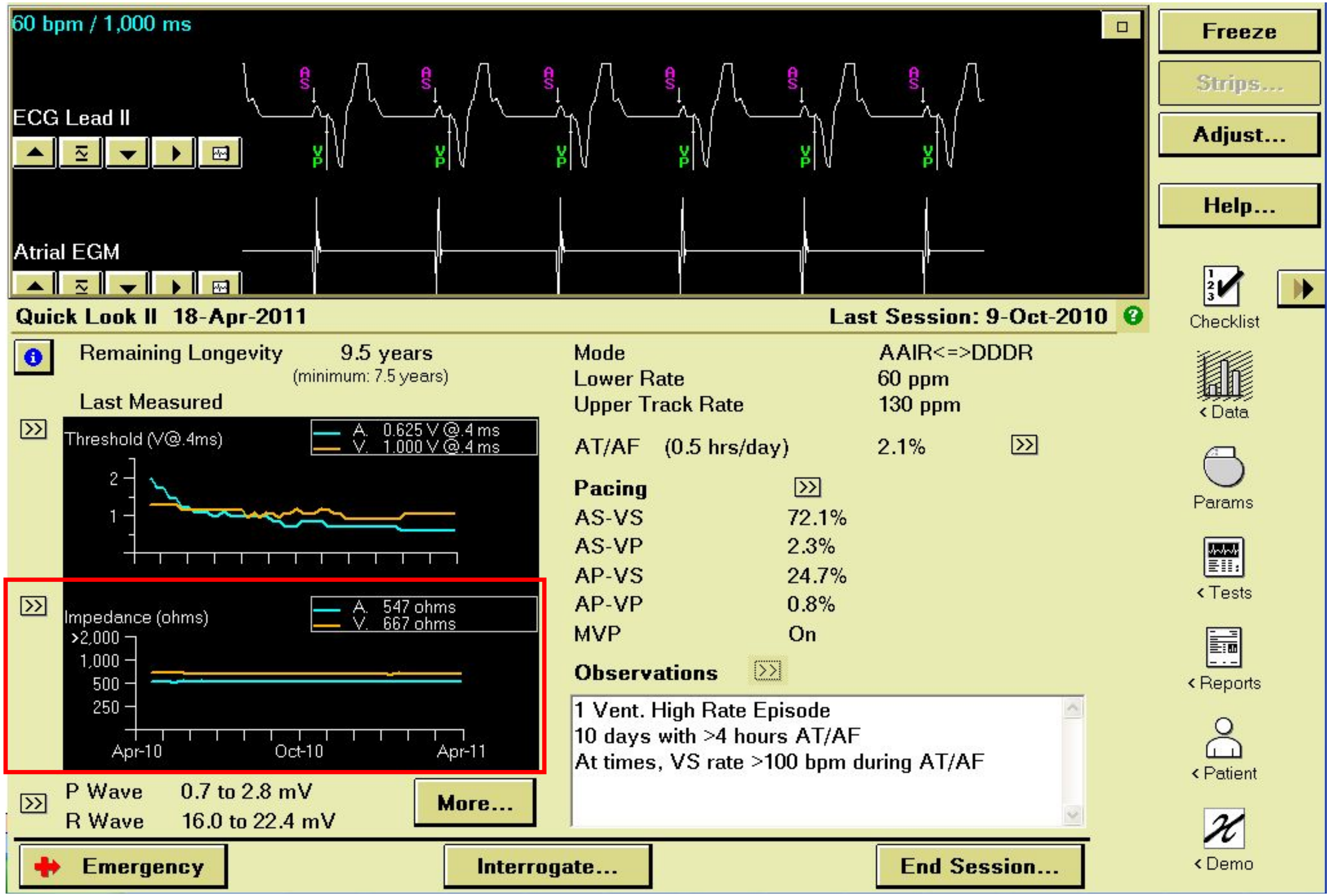
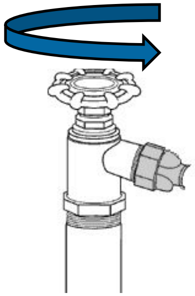
Impedance

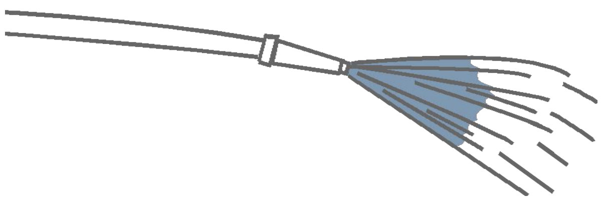

60 bpm / 1,000 ms
ECG Lead II
Atrial EGM
Freeze
Strips...
Adjust...
Help...
Checklist
Quick Look II 18-Apr-2011
Last Session: 9-Oct-2010
Remaining Longevity 9.5 years
(minimum: 7.5 years)
Last Measured
Threshold (V@.4ms)
A. 0.625 V @.4 ms
V. 1.000 V @.4 ms
Impedance (ohms)
A. 547 ohms
V. 667 ohms
>2,000
1,000
500
250
Apr-10
Oct-10
Apr-11
P Wave 0.7 to 2.8 mV
R Wave 16.0 to 22.4 mV
More...
Mode AAIR<=>DDDR
Lower Rate 60 ppm
Upper Track Rate 130 ppm
AT/AF (0.5 hrs/day) 2.1%
Pacing
AS-VS 72.1%
AS-VP 2.3%
AP-VS 24.7%
AP-VP 0.8%
MVP On
Observations
1 Vent. High Rate Episode
10 days with >4 hours AT/AF
At times, VS rate >100 bpm during AT/AF
Data
Params
Tests
Reports
Patient
Demo
Emergency
Interrogate...
End Session...

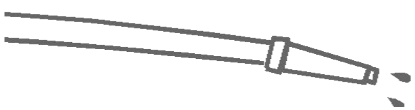
Summary
Voltage, Current, and Impedance

- Voltage: The force moving the current (V)
  - In pacemakers it is a function of the battery chemistry

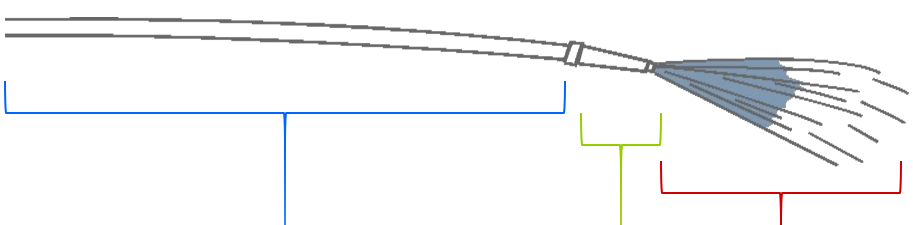


- Current: The actual continuing volume of flow of electricity (I)
  - This flow of electrons causes the myocardial cells to depolarize (to “beat”)



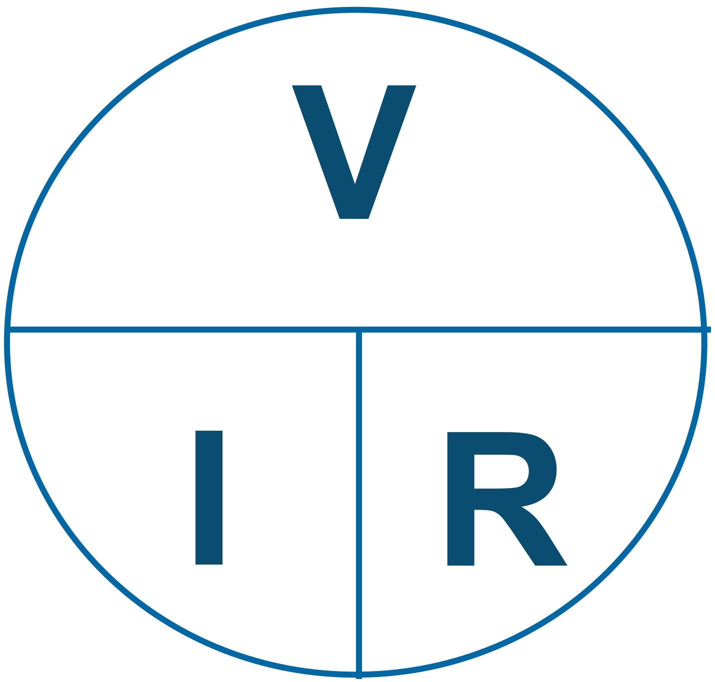


- Impedance: The sum of all resistance to current flow (R)
  - Impedance is a function of the characteristics of the conductor (wire), the electrode (tip), and the myocardium (tissue).

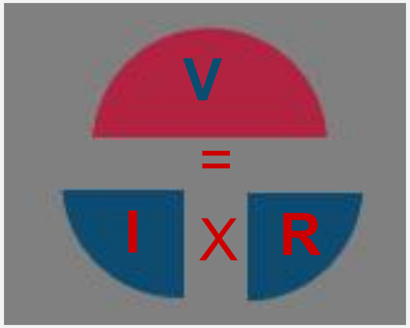


Ohm’s Law

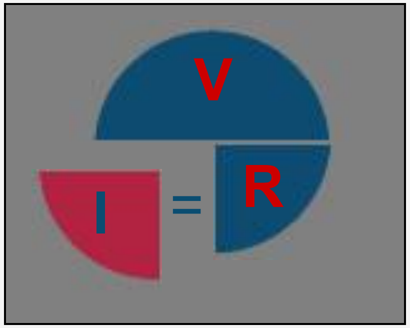
- Describes the relationship between voltage, current, and resistance (impedance)



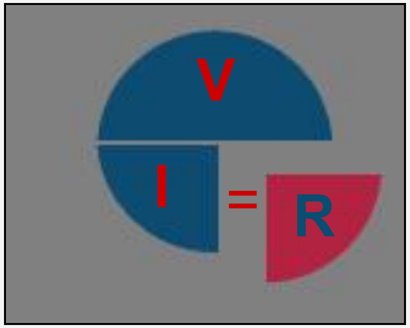
- V = I X R



- I = V / R



- R = V / I



Ohm’s law tells us:

1. If the impedance (R) remains constant, and the voltage decreases, the current decreases
2. If the voltage is constant, and the impedance decreases, the current increases

$$\boxed{V = I \times R}$$

Why is this important to clinical management of pacemakers?

The relationship between voltage, current, and impedance provides the rationale for decisions we make during evaluation of pacing systems and reprogramming. Proper management of electrical characteristics is important for patient safety and device longevity.

Knowledge Checkpoint

What is the delivered current from the Atrial Lead?

Lead Summary	Atrial	Ventricular
Measured Threshold	0.625 V at 0.40 ms	1.000 V at 0.40 ms
Date Measured	04/17/11	04/17/11
Programmed Output	1.500 V / 0.40 ms	2.000 V / 0.40 ms
Capture	Adaptive	Adaptive
Measured P / R Wave	0.7 to 2.8 mV	16.0 to 22.4 mV
Programmed Sensitivity	0.50 mV	5.60 mV
Measured Impedance	547 ohms	667 ohms
Lead Status	OK	OK

Key Learning Points

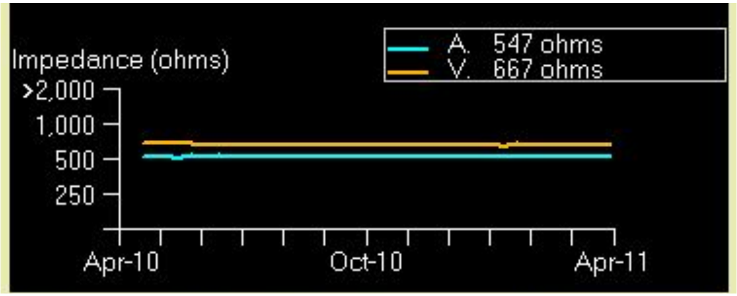
- Know where to find the voltage and impedance on the programmer and report

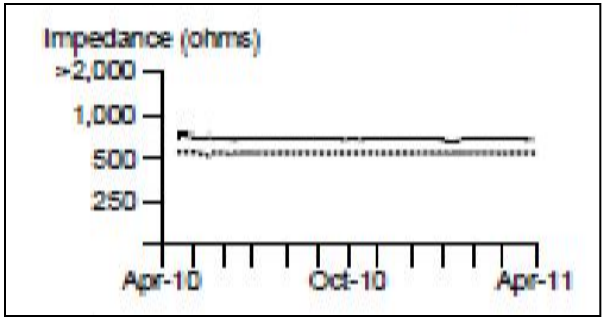
- Ohm's law and the relationship between voltage, current, and impedance
  - Knowing how these factors relate to each other can help you understand how the pacemaker paces the heart

TESTING THE PACEMAKER CIRCUIT

Typical Lead Impedance Range

- Most important that lead impedance is stable over the lifetime of the device.





- Generally, a 30% change or abrupt change is something to be concerned about.

*Typical Impedance range = 200 to 1,000 Ohms.**

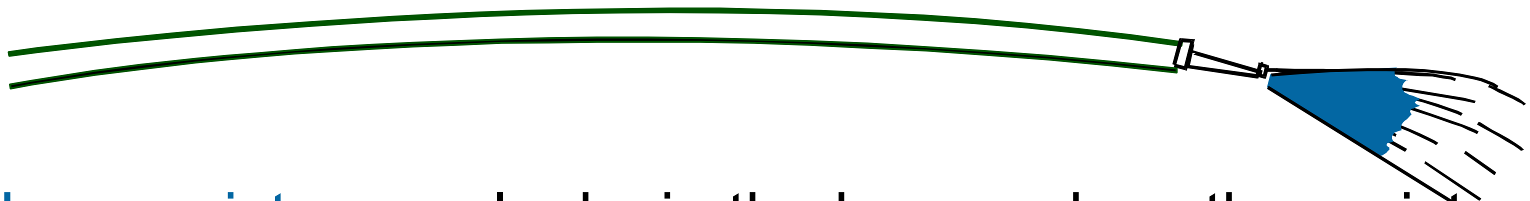
*Impedance is higher for specially designed high impedance leads.

Hayes, David L., et. al. (2000). **Cardiac pacing and defibrillation: a clinical approach.** New York: Blackwell Publishing. (pg. 398).

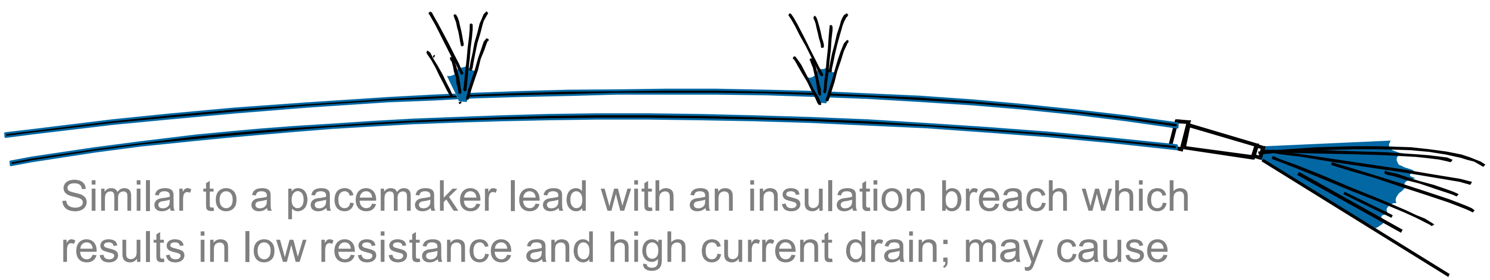
Lead Impedance Values

Electrical Analogies

- Normal resistance – friction caused by the hose and nozzle

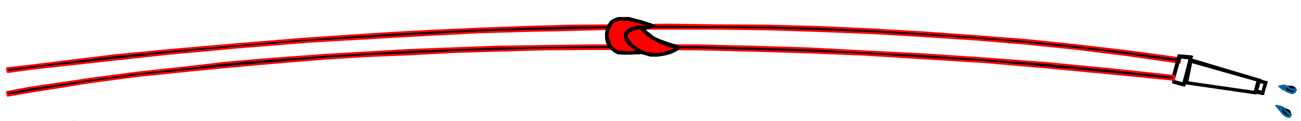


- Low resistance – leaks in the hose reduce the resistance



Similar to a pacemaker lead with an insulation breach which results in low resistance and high current drain; may cause premature battery depletion.

- High resistance – a knot results in low total current flow



Similar to a pacemaker lead with a lead conductor break - impedance will be high with little or no current reaching the myocardium.

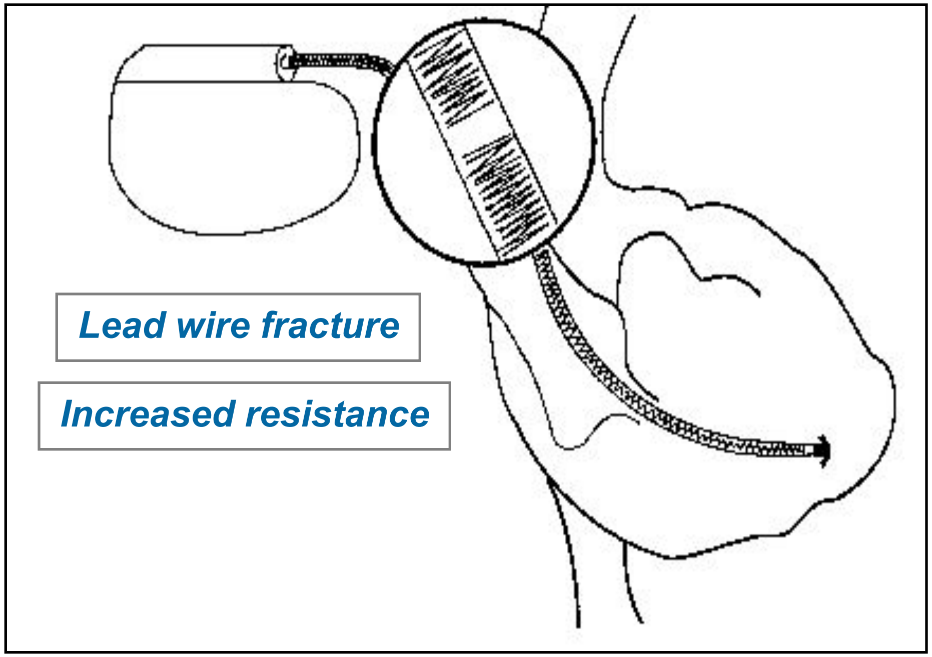
Knowledge Checkpoint

What would you expect to happen if a lead was fractured?

A. Impedance would drop
B. Current would decrease
C. Impedance would rise
D. Both B and C

High Impedance Conditions
A Fractured Conductor

- A fractured wire can cause Impedance values to rise
  - Current flow from the battery may be too low to be effective
- Impedance values may exceed 3,000 Ω



Other reason for high impedance: Lead not seated properly in pacemaker header (usually an acute problem).

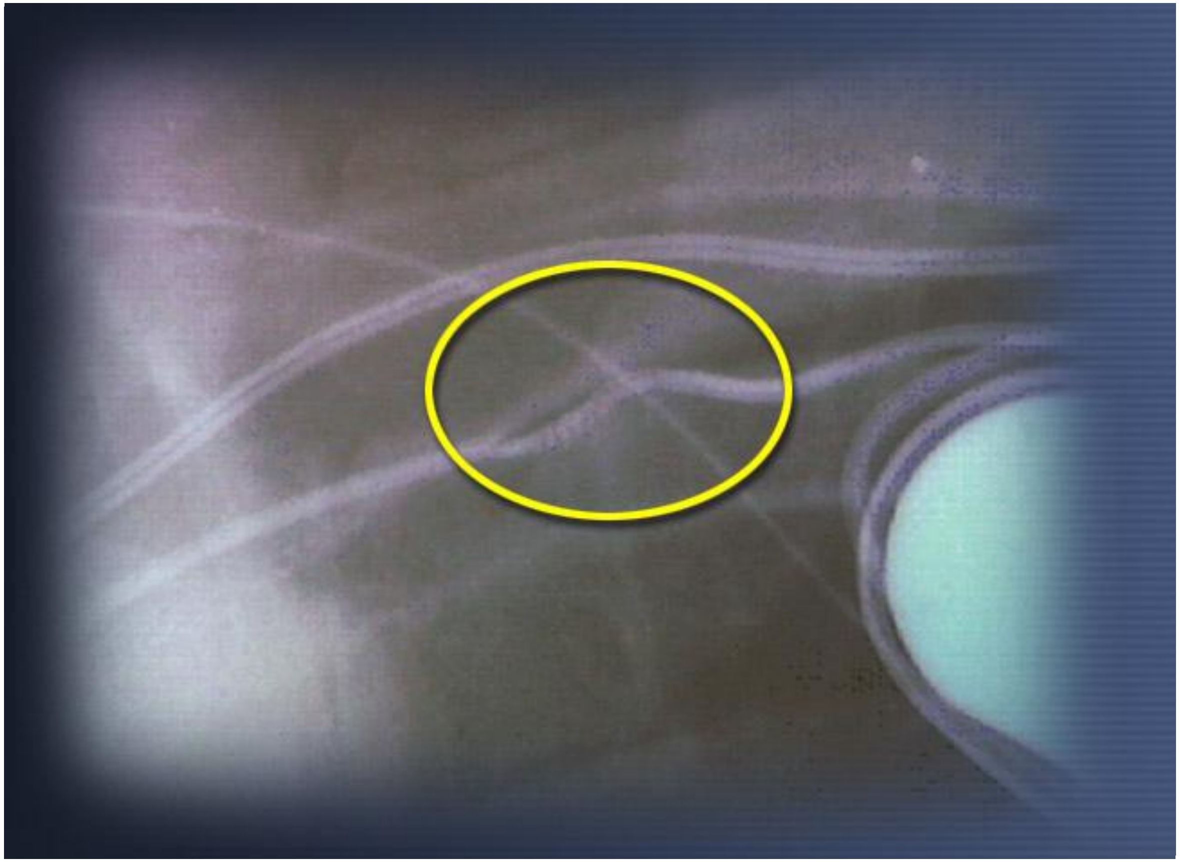
Case Study: Clinic Visit

85 year old male with h/o pacemaker implant in 1996. Generator change in 2005. Follow up visits in clinic have been normal. He now comes into your office complaining of light-headedness and fatigue.

- You interrogate his pacemaker and find the ventricular lead impedance is 1,867 ohms and it was usually trending around 700 ohms.

Chest X Ray

Can you identify a problem?



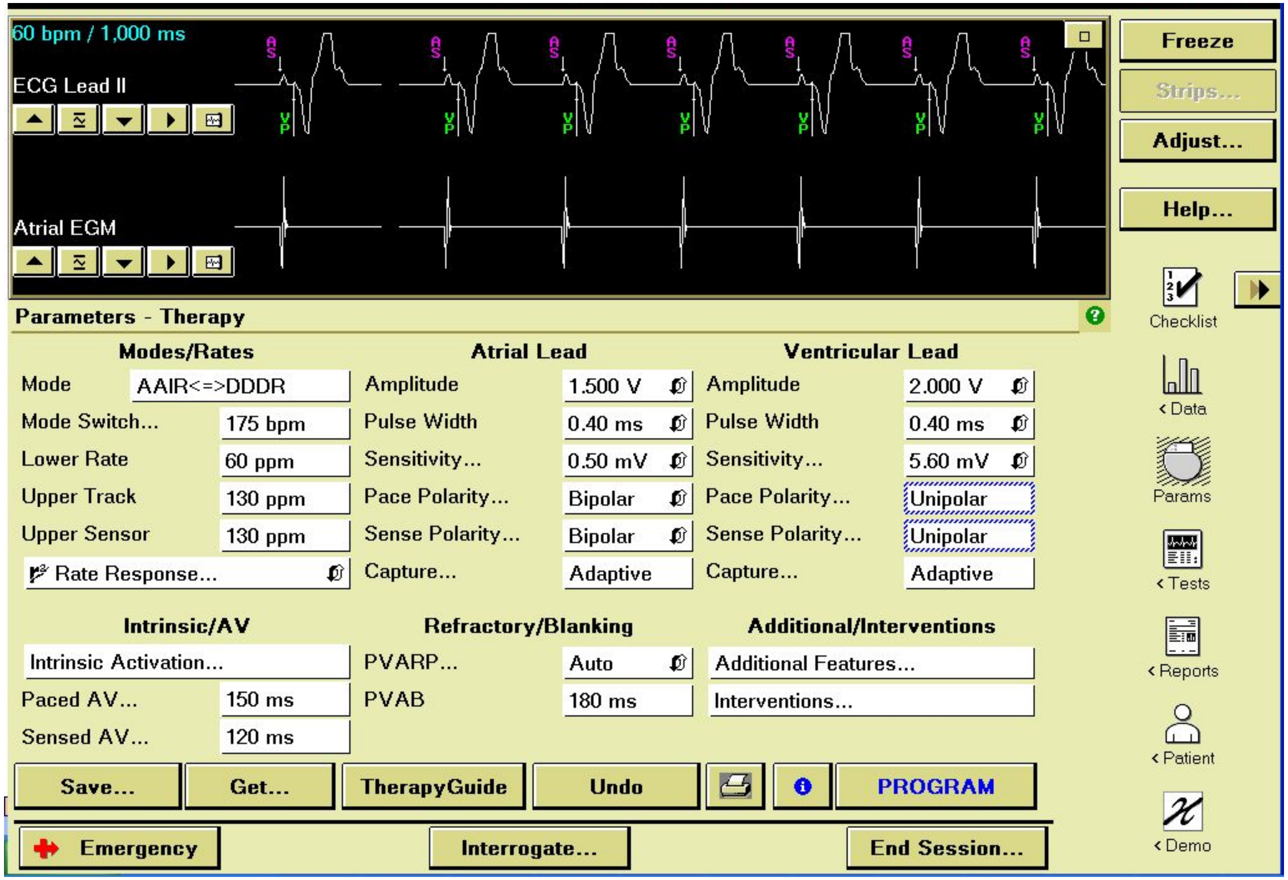
1st Rib-Clavicle Crush (lead fracture)

Lead Crush

Now that you know what the problem is,
How do you fix it?

Solutions for Lead Crush

- Unipolar configuration if the inner conductor is still intact
- Lead replacement



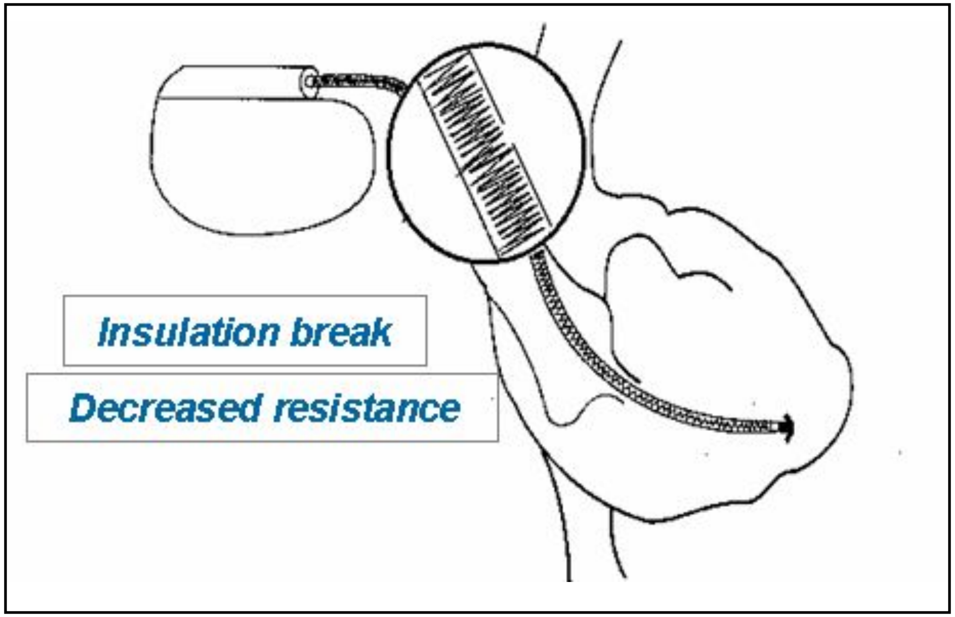
Knowledge Checkpoint

What would you expect to happen if a lead has an insulation break? Check all that apply.

- ❑Impedance would drop
- ❑Potential loss of capture
- ❑Current would increase
- ❑Battery longevity improves

Low Impedance Conditions
An Insulation Break

- Insulation breaks can cause impedance values to fall
  - Current drain is high and can lead to more rapid battery depletion
  - Current can drain through the insulation break into the body or other lead wire, not through myocardium
- Impedance values may be less than 300 Ω



Current will follow the path of LEAST resistance

Case Study: Routine Follow Up

- A patient comes in for routine follow up and you notice this on the initial interrogation report:

Battery and Lead Measurements Report

Battery Status 02/29/08 5:07:31 PM

Battery Status	OK
Voltage	2.75 V
Current	25.53 µA
Impedance	100 ohms

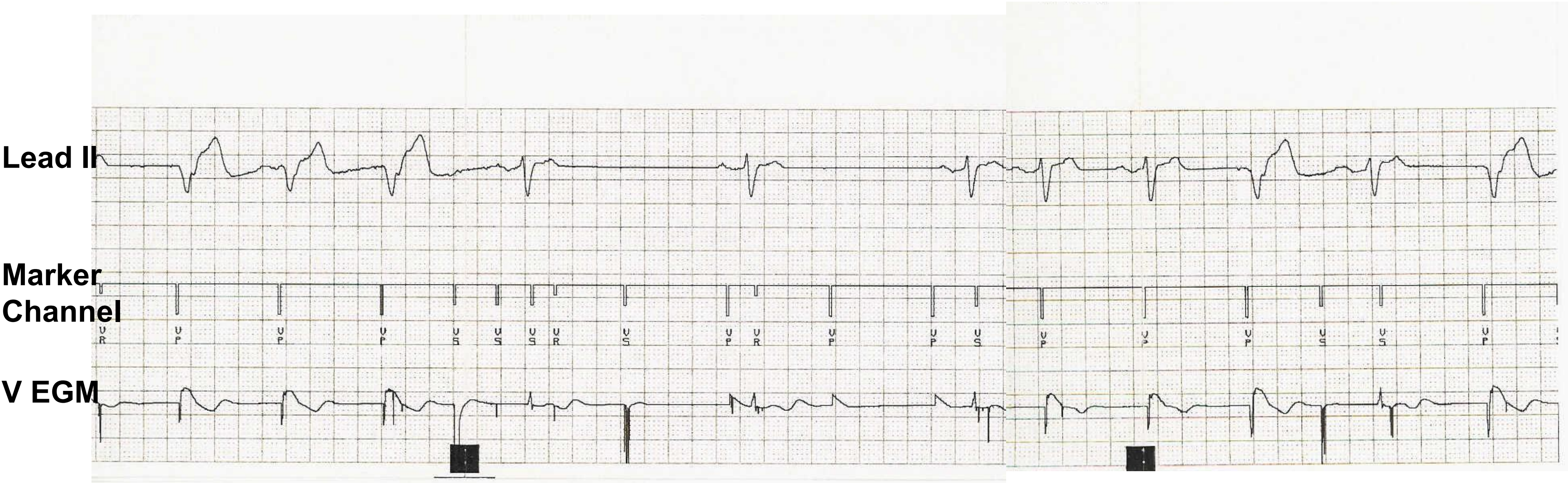
Remaining Longevity

Minimum	4 years
Maximum	6 years
Based on 100% Pacing	

Lead Status 02/29/08 5:07:31 PM

	Atrial	Ventricular
Amplitude	3.85 V	3.63 V
Pulse Width	0.40 ms	0.40 ms
Output Energy	8.72 µJ	18.22 µJ
Current	6.03 mA	14.75 mA
Impedance	598 ohms	207 ohms
Pace Polarity	Bipolar	Unipolar

Look at the EGM



- What do you suspect?

Insulation Break

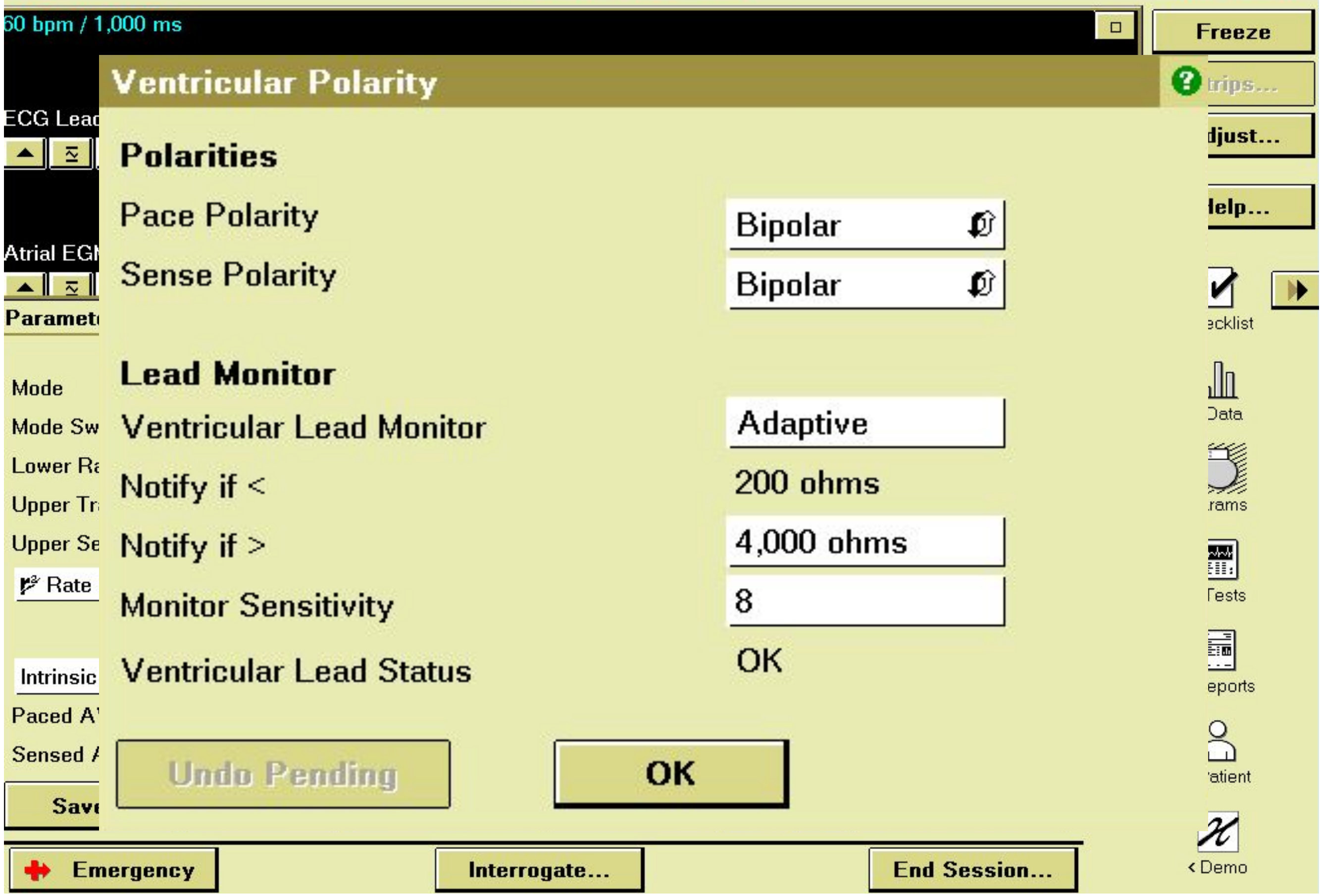
- A low impedance usually means an insulation break
- Oversensing can be a result of an insulation break and the EGM shows abnormal electrical signals

Now that we know what the problem is,

how do you fix it?

Polarity Switch

- The automatic “Polarity Switch” of the pacemaker can automatically notice an issue with the lead impedance and switch to unipolar

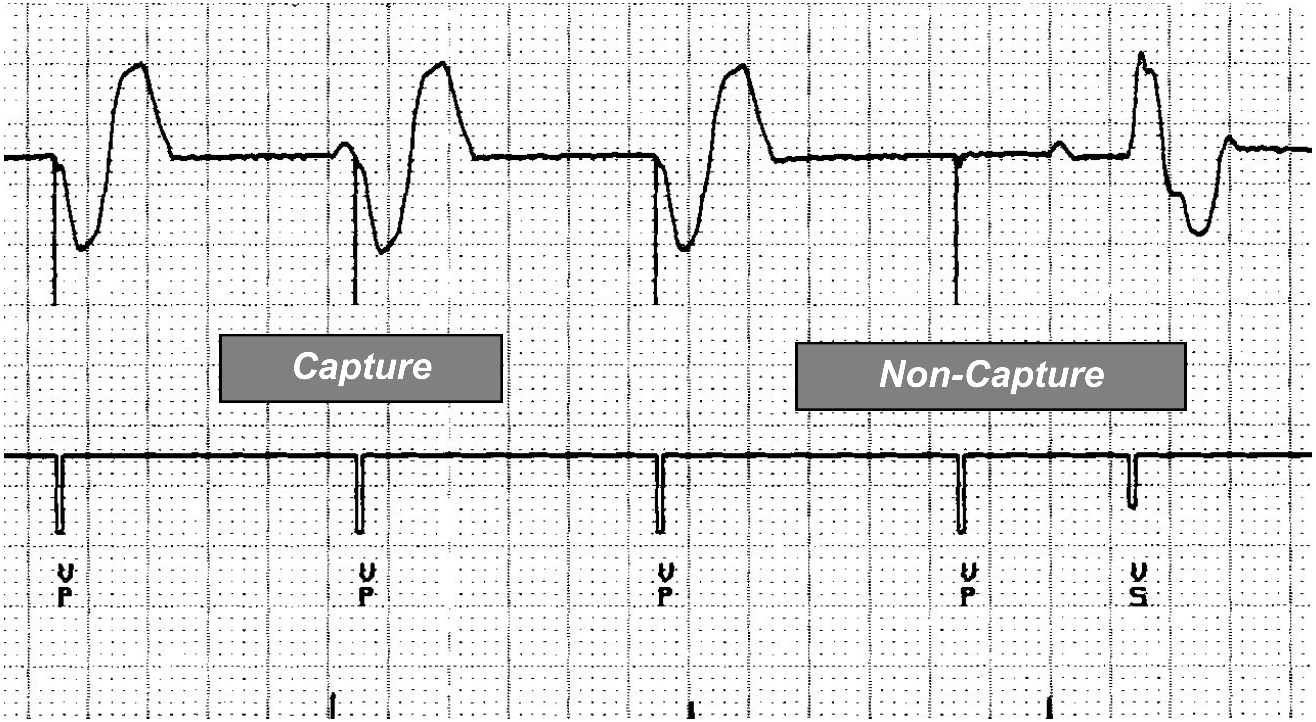


Replace the Lead

- Since the lead is still oversensing and has a low impedance in the unipolar configuration, a lead replacement still should be performed.
- The lead can be capped and a new ventricular pacing lead can be placed at least 1 cm away to prevent lead-lead noise.

Capture Threshold

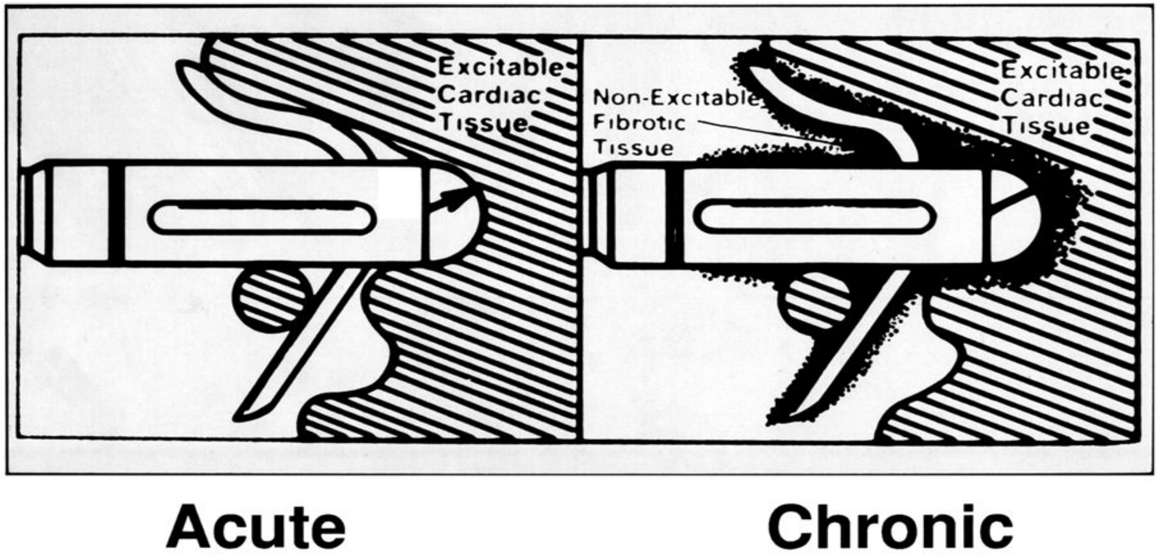
- The minimum electrical stimulus needed to consistently capture the heart outside of the heart’s own refractory period



Ventricular pacemaker 60 ppm

Effect of Lead Design on Capture

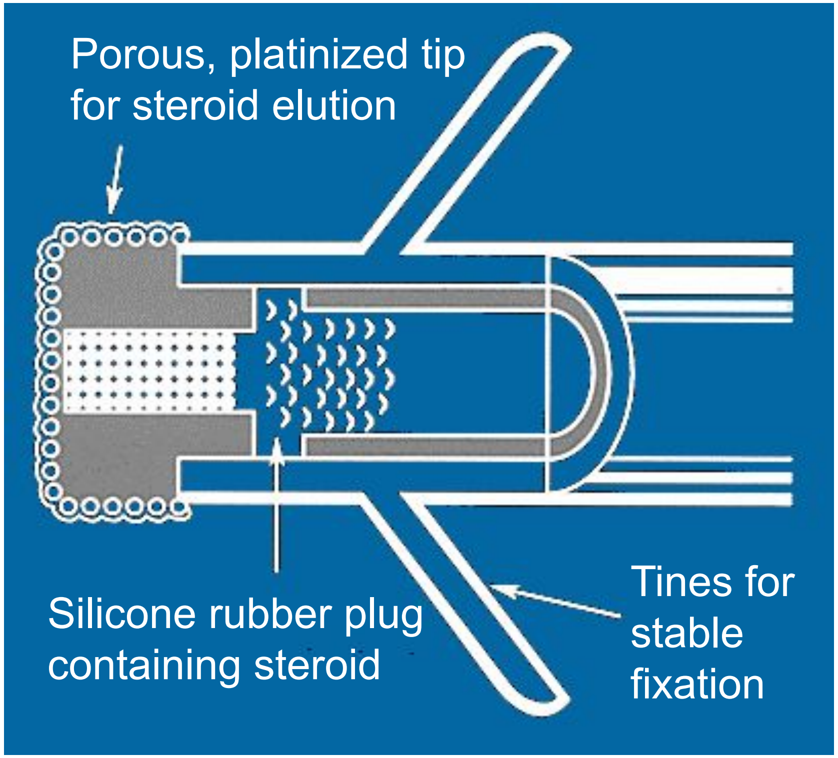
- Lead maturation
  - Fibrotic “capsule” develops around the electrode following lead implantation
  - May gradually raise threshold
  - Usually no measurable effect on impedance



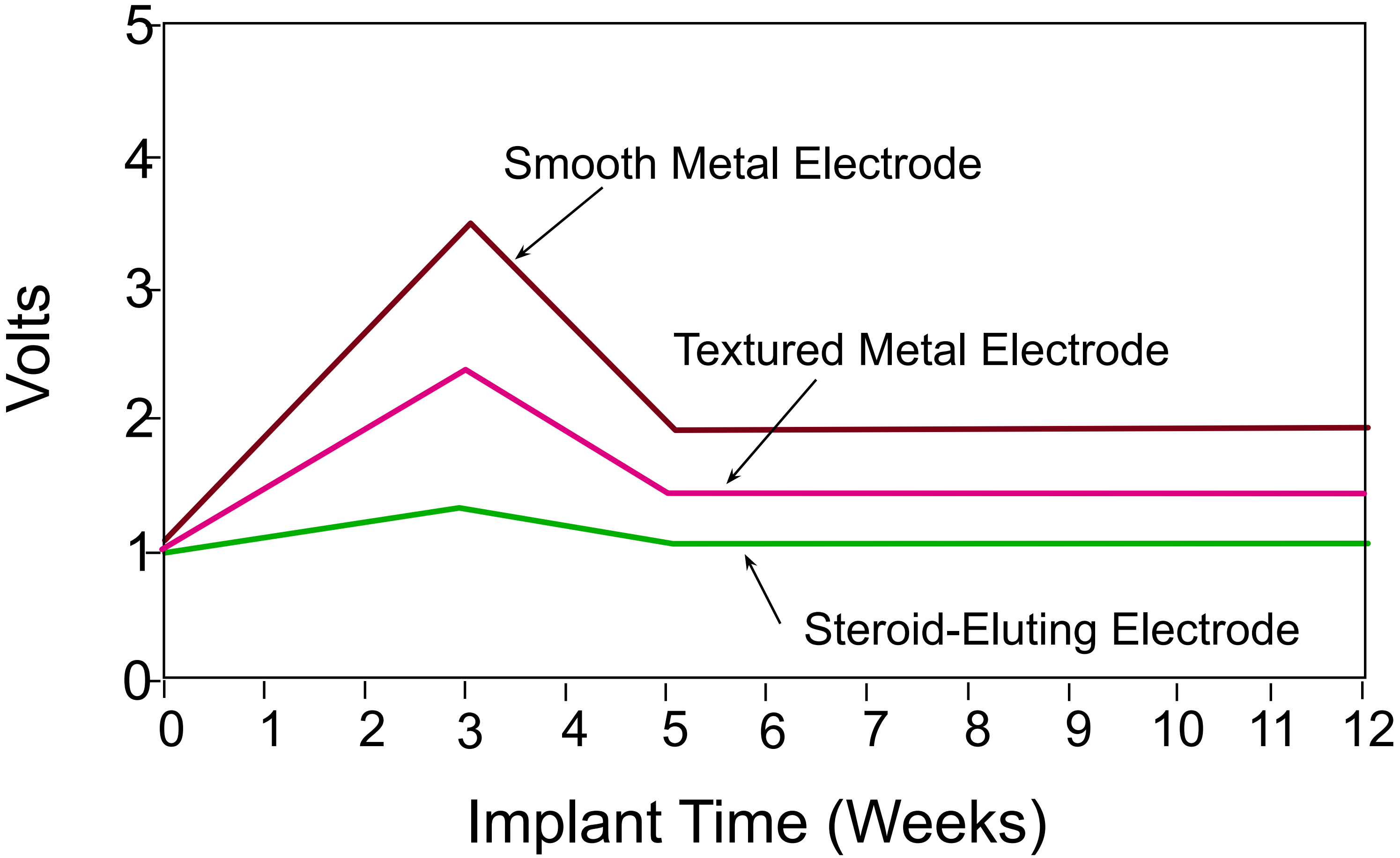
Ellenbogen, Kenneth A. and Mark A. Wood. (2005). **Cardiac Pacing and ICDs.** Massachusetts: Blackwell Publishing. (pg. 342).

Steroid Eluting Leads

- Steroid eluting leads reduce the inflammatory process
  - Exhibit little to no acute stimulation threshold peaking
  - Leads maintain low chronic thresholds



Effect of Steroid on Stimulation Thresholds



Pulse Width = 0.5 msec

References: Pacing Reference Guide, Bakken Education Center, 1995, UC199601047aEN. Cardiac Pacing, 2nd Edition, Edited by Kenneth A. Ellenbogen. 1996.

Factors That Can Affect Thresholds

- Pacemaker circuit (lead) integrity
  - Insulation break
  - Wire fracture
- The characteristics of the electrode
- Electrode placement within the heart
- Drugs
- Electrolytes
- Sleeping/Eating

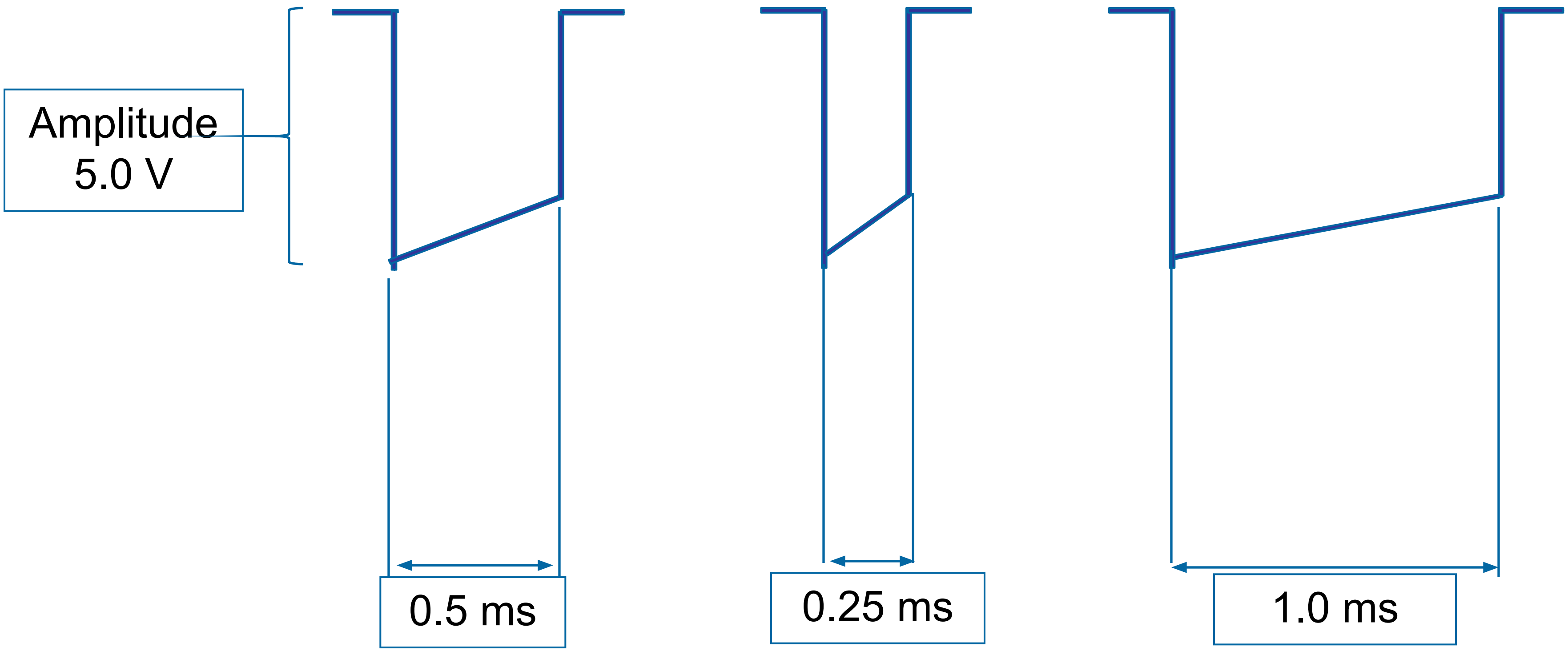
Hayes, Cardiac Pacing and Defibrillation, 2010

Myocardial Capture

- Capture is a function of:
  - Amplitude—the strength of the impulse expressed in volts
    - The amplitude of the impulse must be large enough to cause depolarization (i.e., to “capture” the heart)
    - The amplitude of the impulse must be sufficient to provide an appropriate pacing safety margin
  - Pulse width—the duration of the current flow expressed in milliseconds
    - The pulse width must be long enough for depolarization to disperse to the surrounding tissue

Comparison

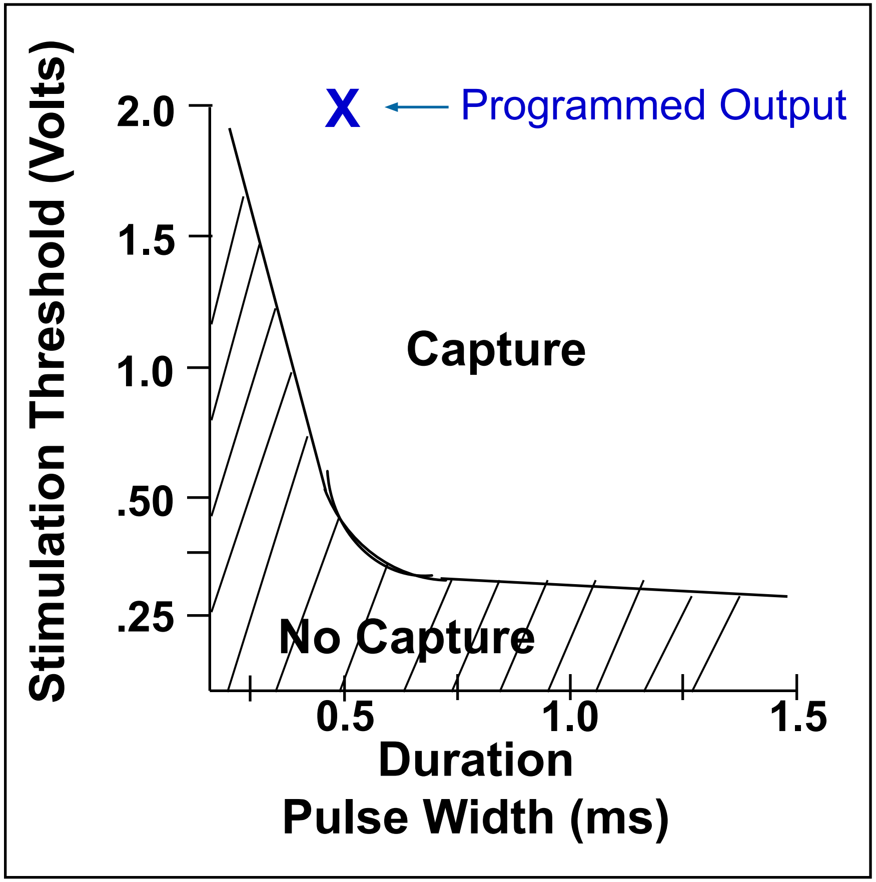
5.0 Volt Amplitude at Different Pulse Widths



Strength-Duration Curve

- Strength-duration curve shows relationship of amplitude and pulse width

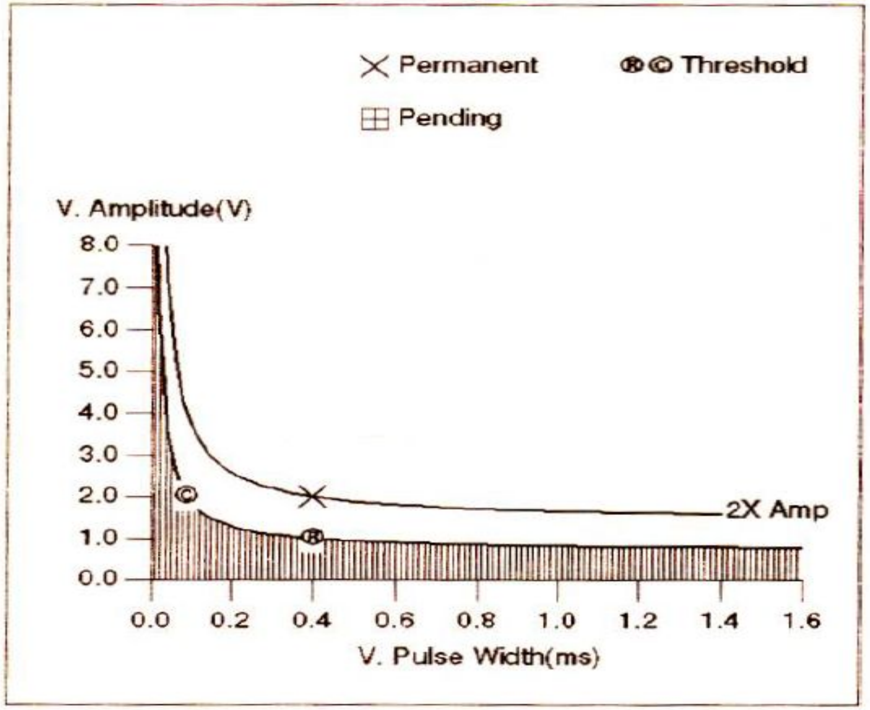
- Adequate safety margins are important because thresholds can fluctuate slightly



Strength Duration Curve Example

Strength Duration Threshold Test Report Page 1

Ventricular Strength Duration Threshold Test Report Collected: 03/05/07 4:43:17 PM



Pending values provide:

Amplitude Safety Margin of 2.00 X

Estimated battery life of 60 months

	Pending	Permanent
Amplitude	2.000 V	2.000 V
Pulse Width	0.40 ms	0.40 ms

Measured Threshold: 1.000 V at 0.40 ms

Safety Margin = 2 x Amplitude Threshold

OR

3 x Pulse Width Threshold

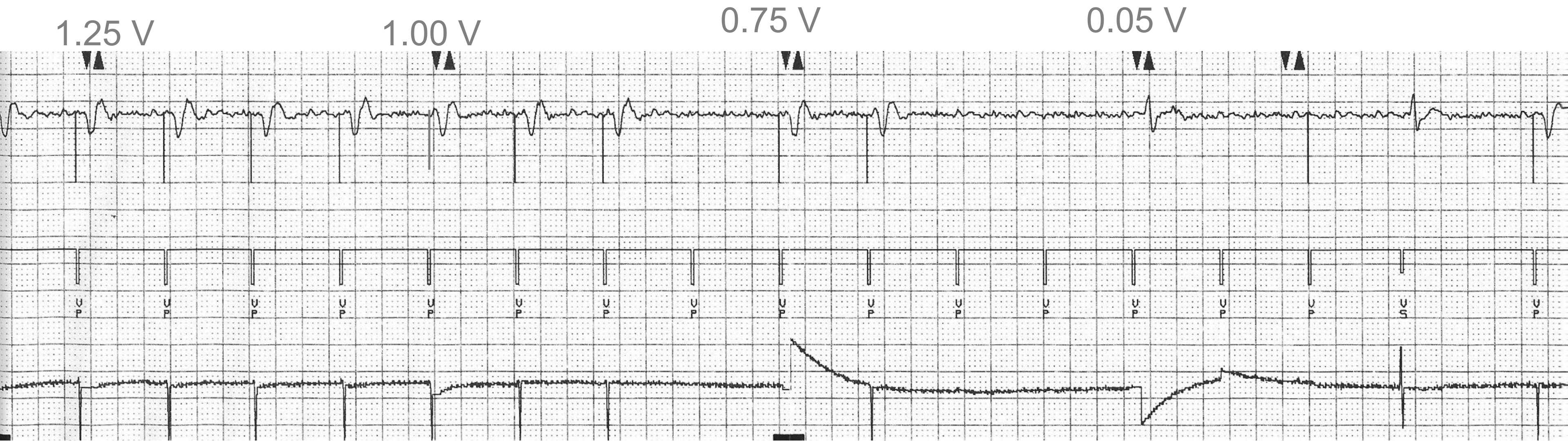
Programming Outputs

- Primary goal: Ensure patient safety and appropriate device performance

- Secondary goal: Extend the service life of the battery
  - Typically program amplitude to $\leq$ 2.5 V, but always maintain adequate safety margins
  - Amplitude values greater than the cell capacity of the pacemaker battery (usually about 2.8 V) require a voltage multiplier, resulting in markedly decreased battery longevity

Knowledge Checkpoint

What is the threshold?



A. 0.05 V

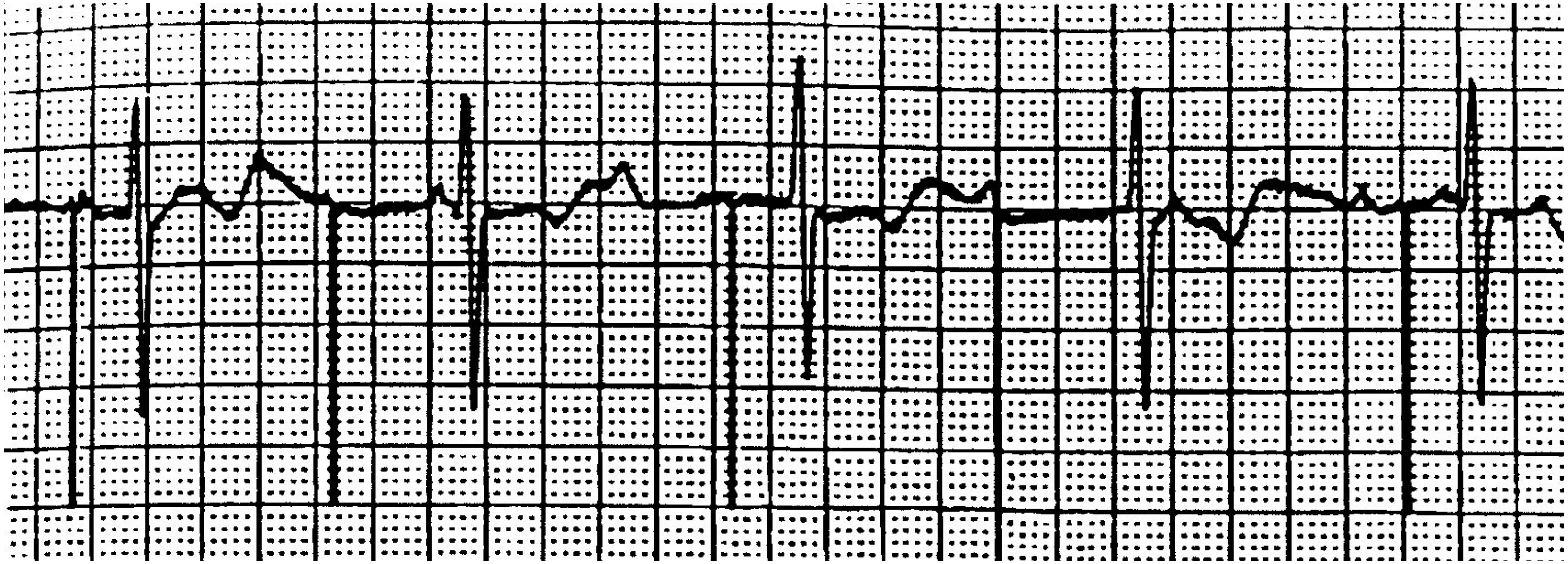
B. 0.75 V

C. 1.00 V

D. 1.25 V

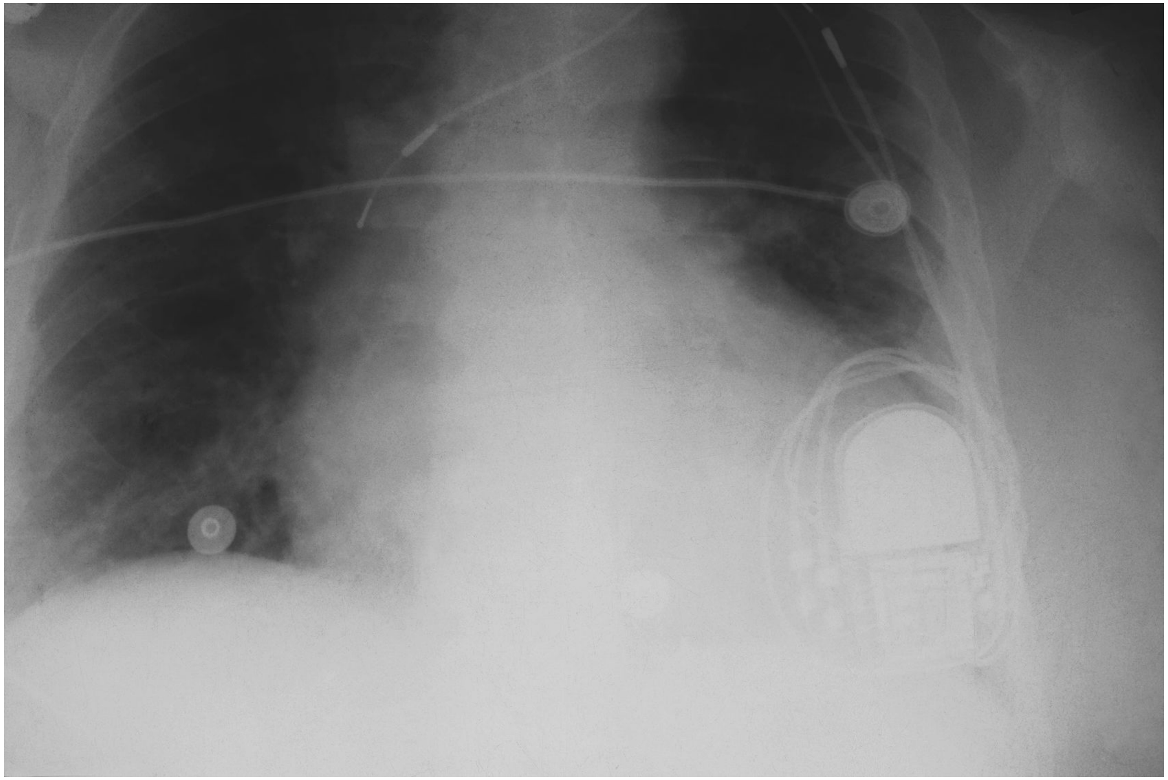
Case Study: ER Visit

A patient presented to the ER with the complaint that he felt just the way he did when he first received his pacemaker. What is your interpretation?

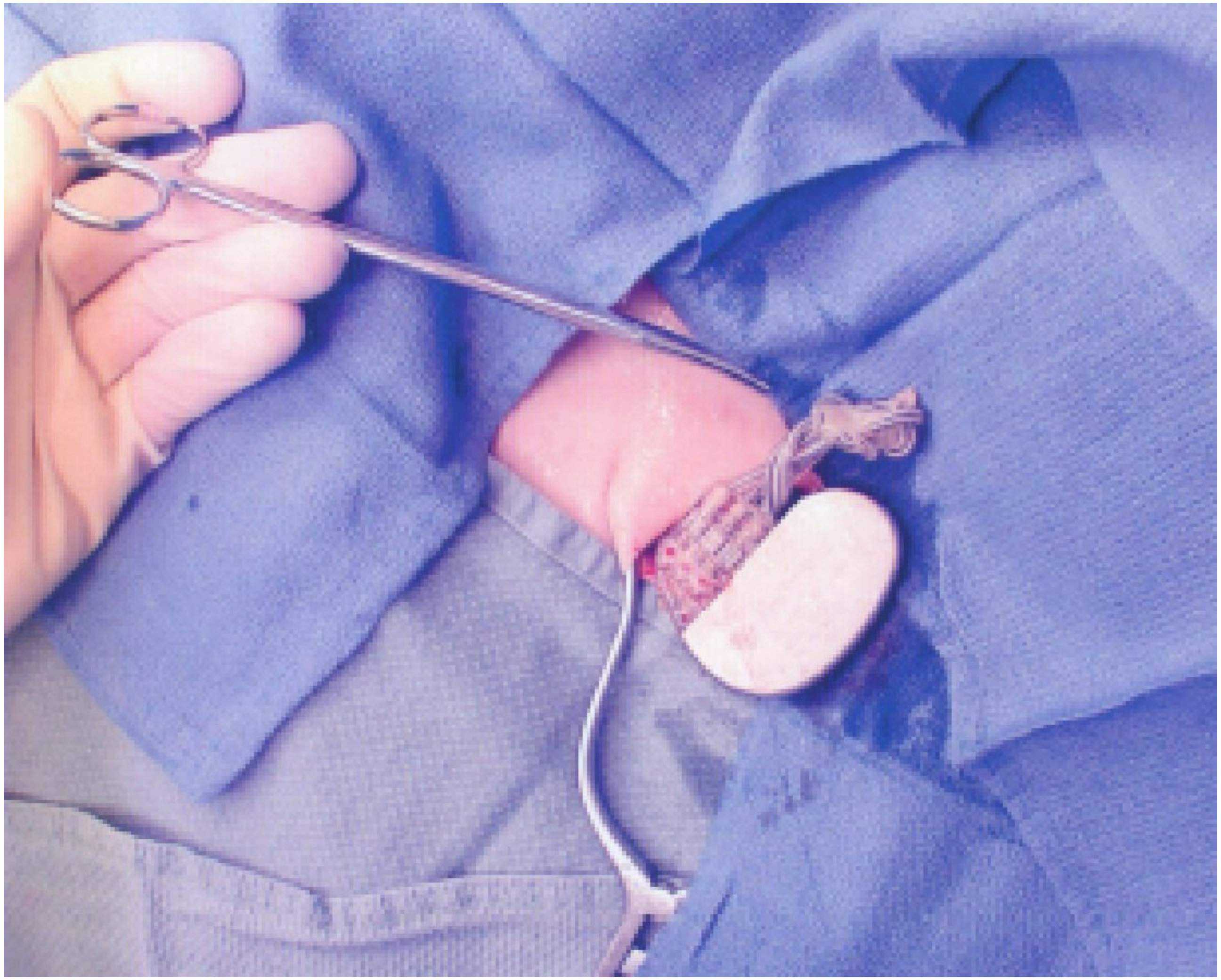


Order a Chest X-ray

The chest x-ray revealed a dislodged lead



Twiddler's Syndrome

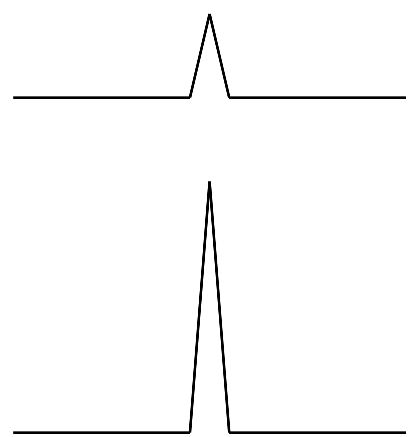


Sensing

- Sensing is the ability of the pacemaker to “see” when a natural (intrinsic) depolarization is occurring
  - Pacemakers sense cardiac depolarization by measuring changes in electrical potential of myocardial cells between the anode and cathode

0.5 mV signal

2.0 mV signal



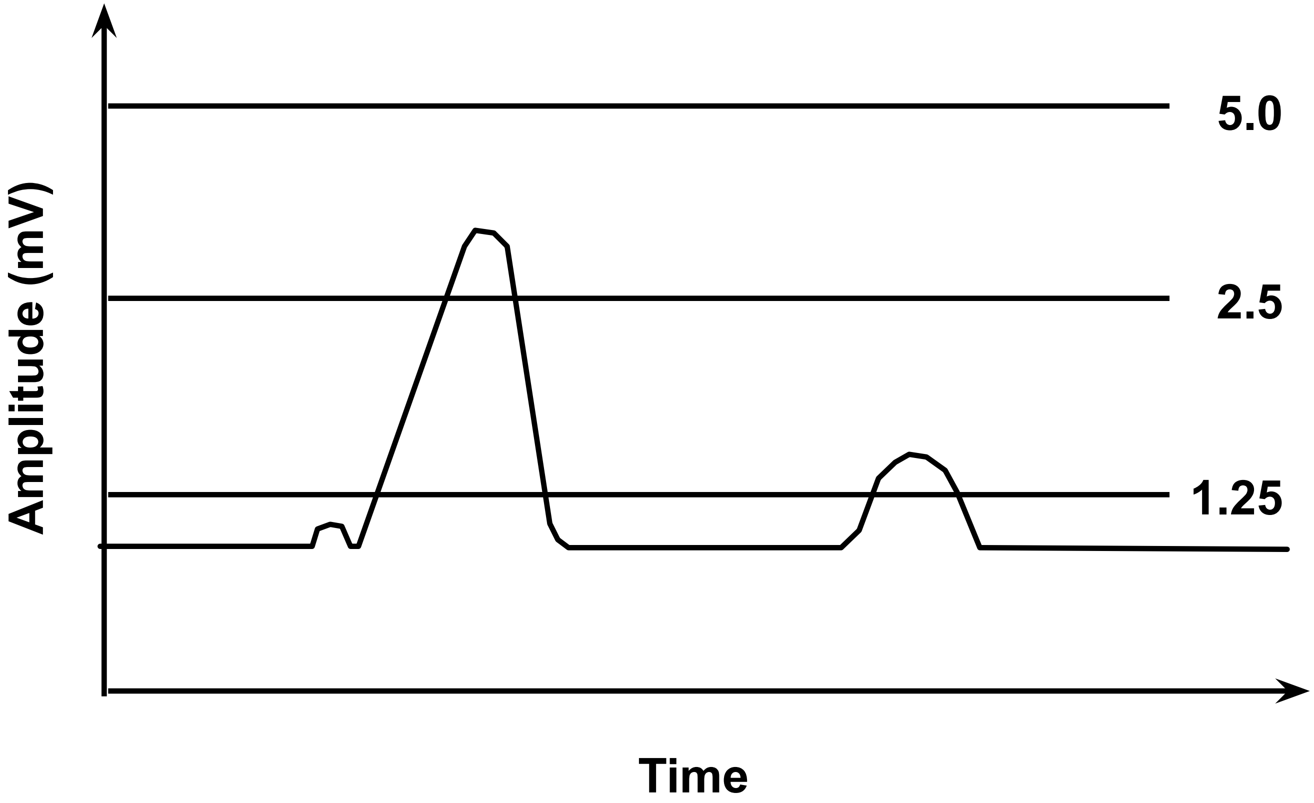
Sensing

Acceptable Sensing Values (mV)[1]

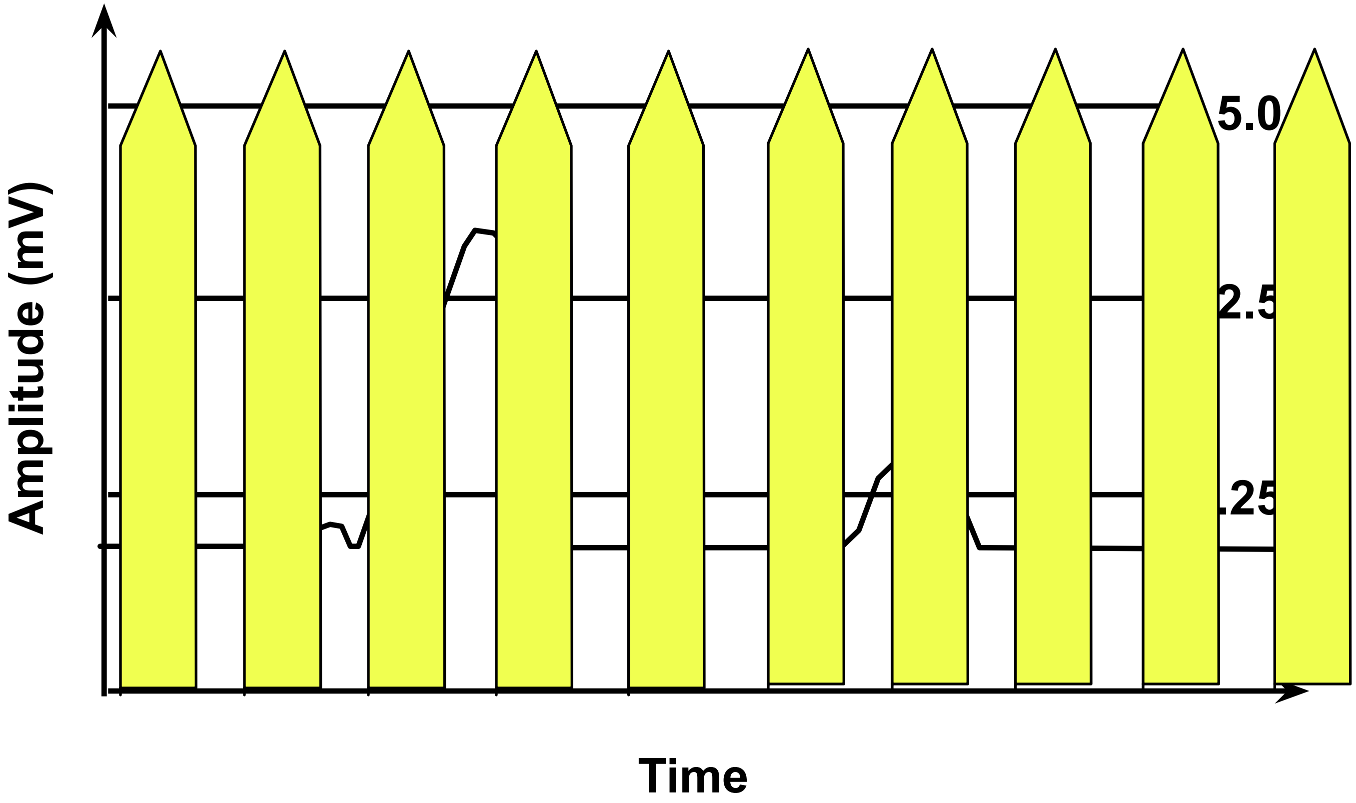
	Acute	Chronic
Atrium	>1.5	>1.0
Ventricle	>7.0	>5.0

[1]Curtis, Anne B. (2010). **Fundamentals of Cardiac Pacing.** Massachusetts: Jones and Bartlett Publishers. (pg. 98).

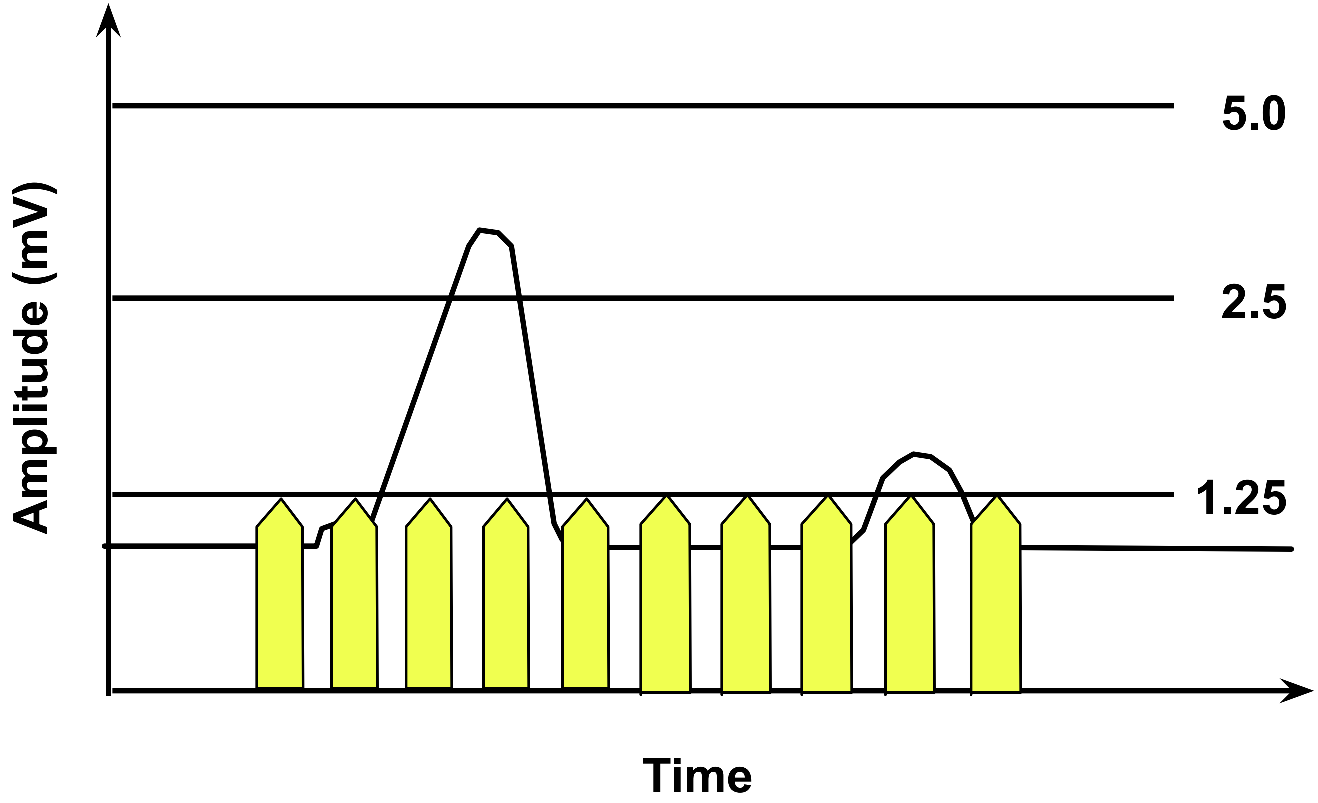
Sensitivity



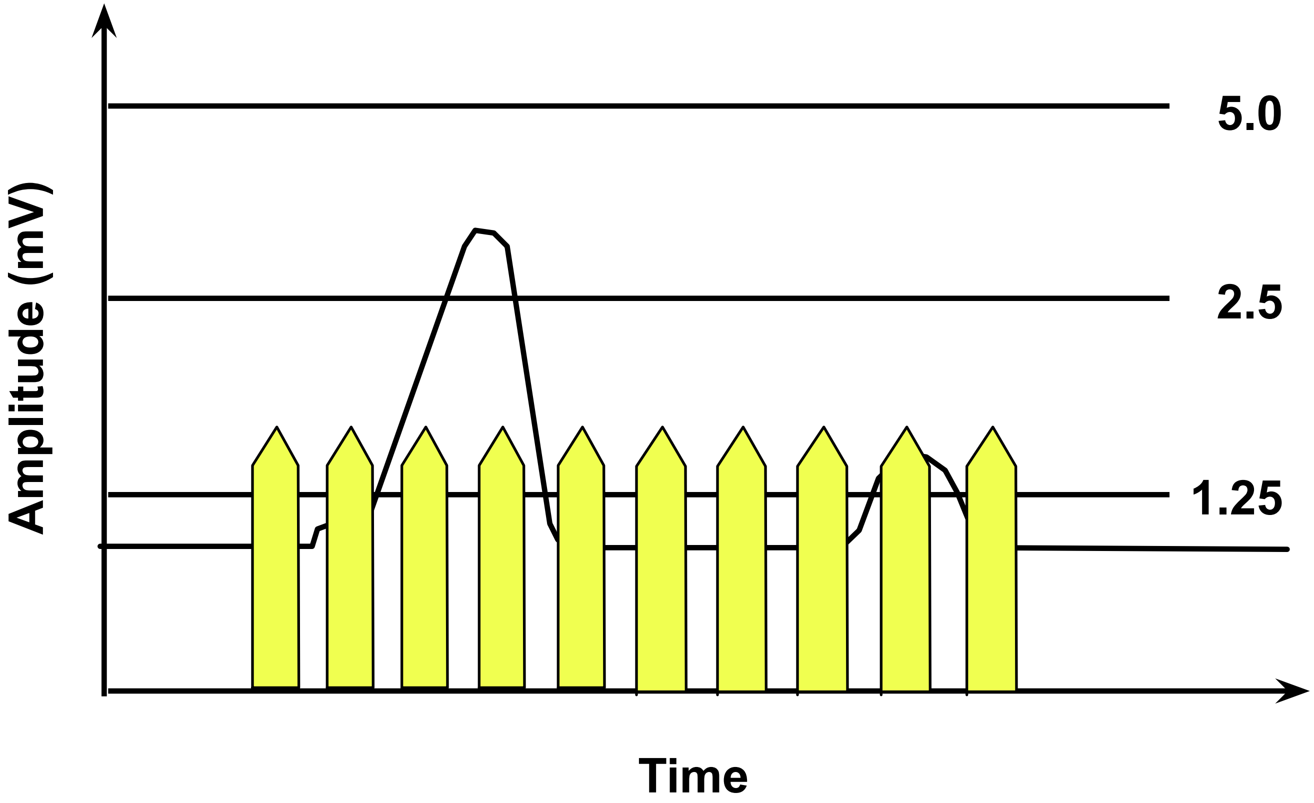
Less Sensitive = High Sensitivity Number



More Sensitive = Low Sensitivity Number



Adequate Sensitivity

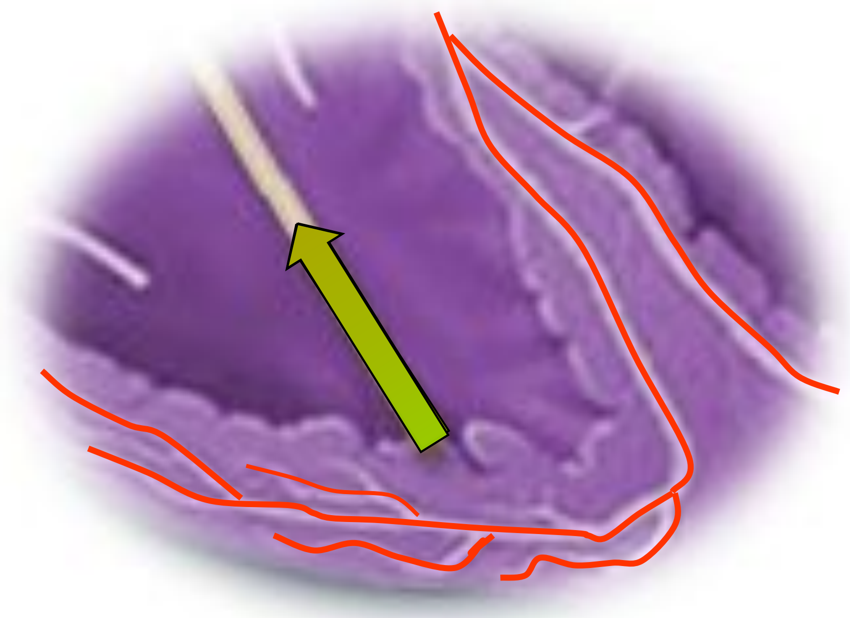


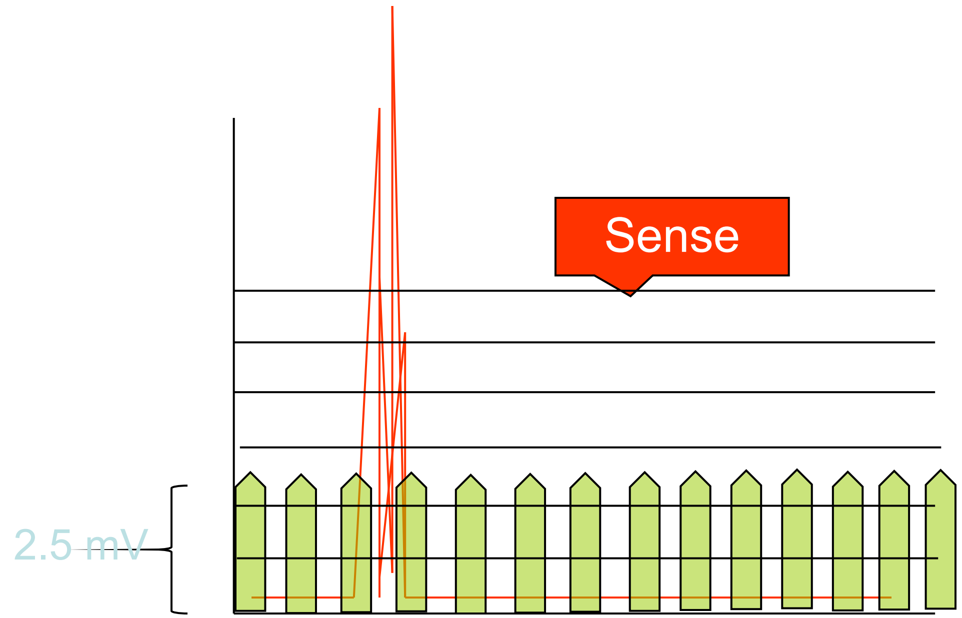
Sensing Amplifiers/Filters

- Accurate sensing requires that extraneous signals are filtered out
  - Because whatever a pacemaker senses is by definition a P- or an R-wave
  - Sensing amplifiers use filters that allow appropriate sensing of P- and R-waves, and reject inappropriate signals

- Unwanted signals most commonly sensed are:
  - T-waves (which the pacemaker defines as an R-wave)
  - Far-field events (R-waves sensed by the atrial channel, which the pacemaker thinks are P-waves)
  - Skeletal muscle myopotentials (e.g., from the pectoral muscle, which the pacemaker may think are either P- or R-waves)
  - Signals from the pacemaker (e.g., a ventricular pacing spike sensed on the atrial channel "crosstalk")

Vectors and Gradients

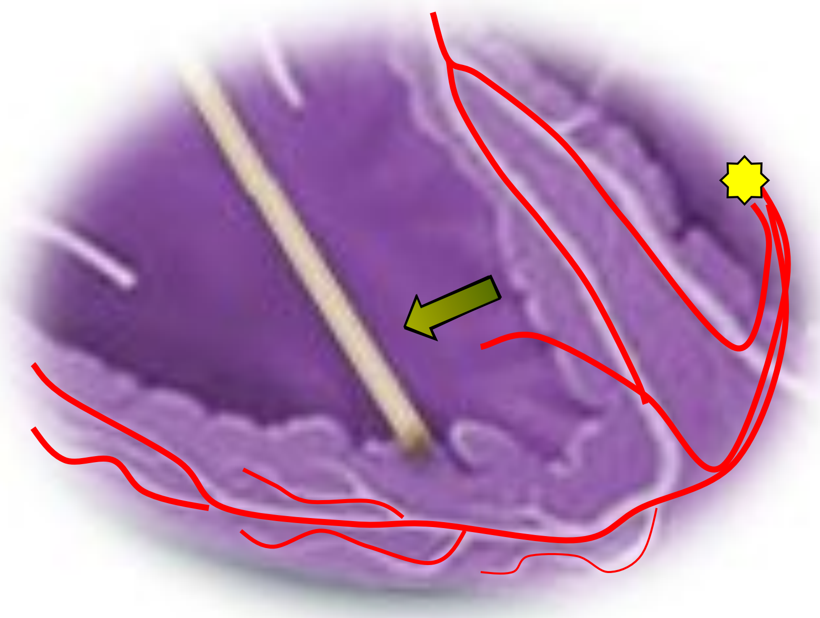


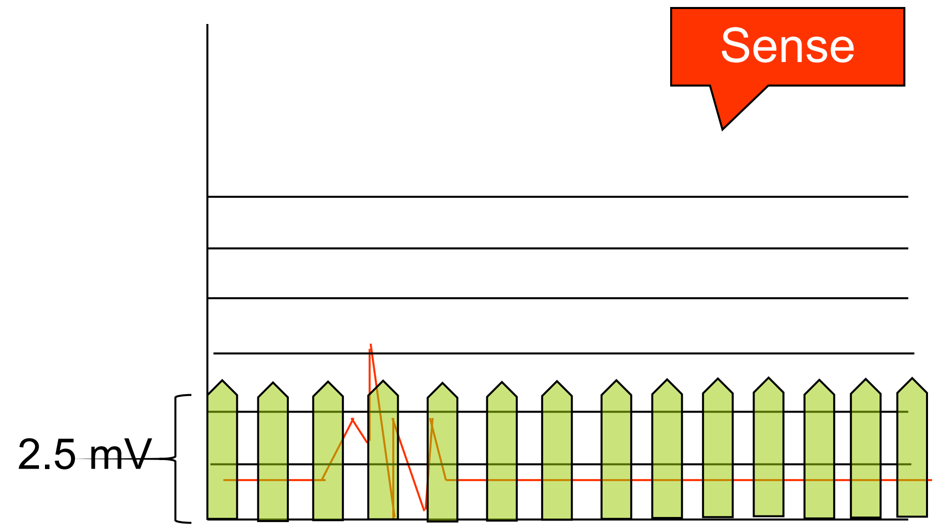


The wave of depolarization produced by normal conduction creates a gradient across the cathode and anode. This changing polarity creates the signal.

Once this signal exceeds the programmed sensitivity – it is sensed by the device.

Changing the Vector





A PVC occurs, which is conducted abnormally. Since the vector relative to the lead has changed, what effect might this have on sensing?

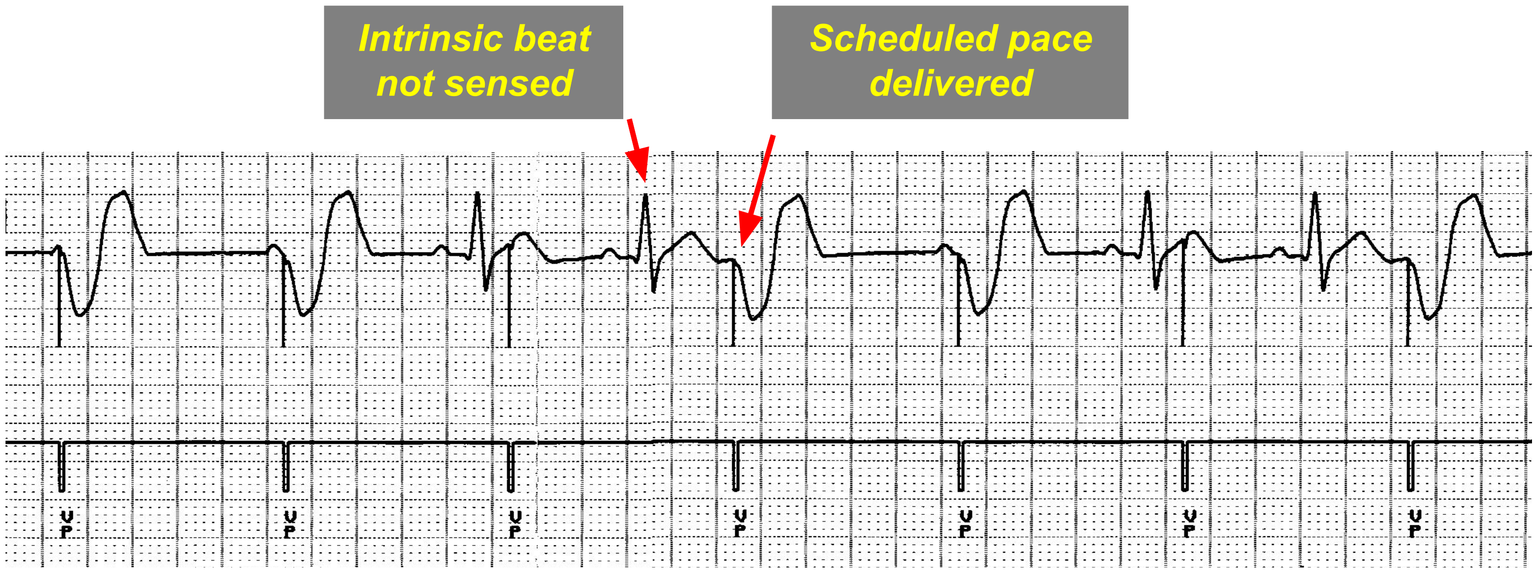
In this case, the wave of depolarization strikes the anode and cathode almost simultaneously. This will create a smaller gradient and thus, a smaller signal.

Sensing Accuracy

- Affected by:
  - Pacemaker circuit (lead) integrity
    - Insulation break
    - Wire fracture
  - The characteristics of the electrode
  - Electrode placement within the heart
  - The sensing amplifiers of the pacemaker
  - Lead polarity (unipolar vs. bipolar)
  - The electrophysiological properties of the myocardium
  - EMI – Electromagnetic Interference

Undersensing . . .Overpacing

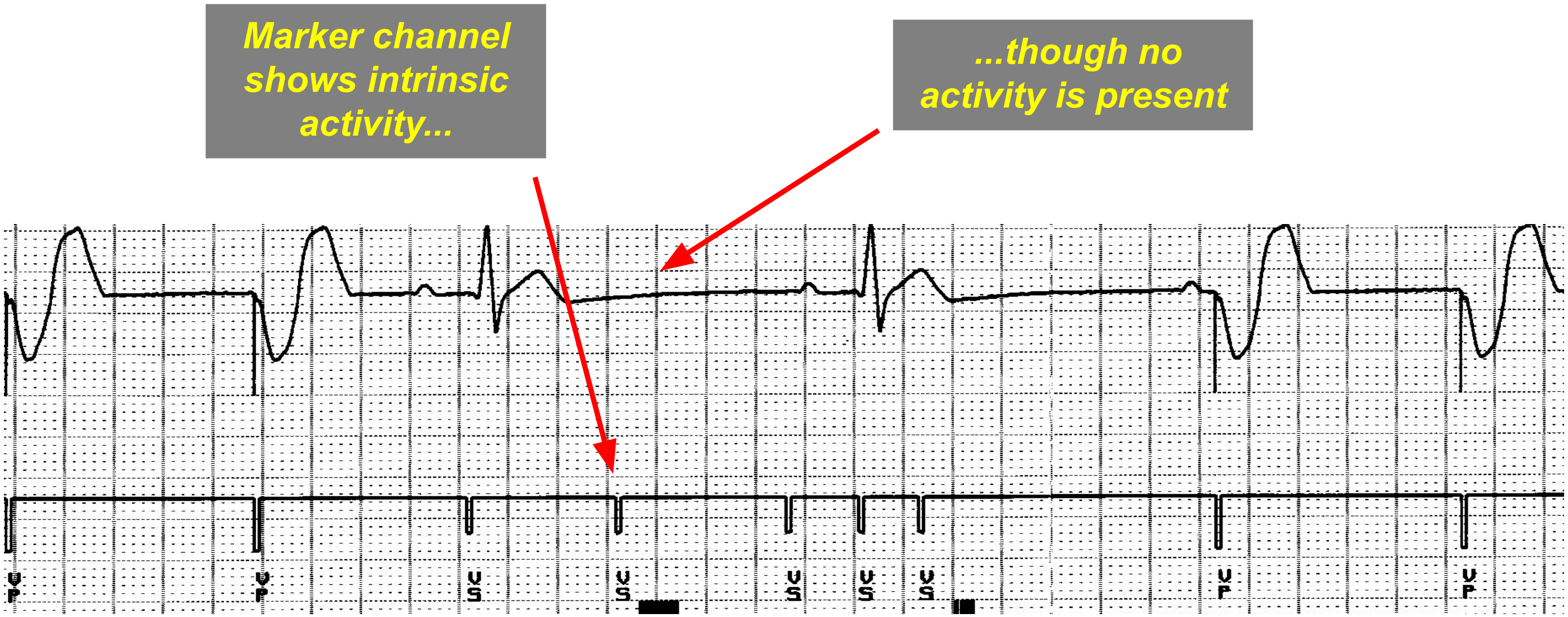
- Pacemaker does not “see” the intrinsic beat, and therefore does not respond appropriately



VVI / 60

Oversensing …Underpacing

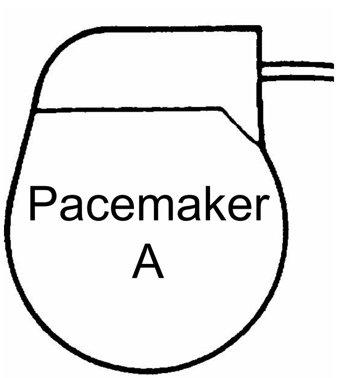
- An electrical signal other than the intended P or R wave is detected



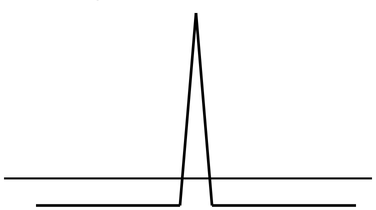
VVI / 60

Knowledge Checkpoint

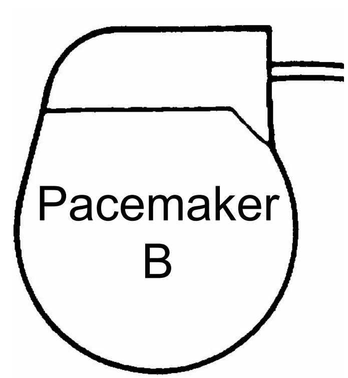
Which of these pacemakers is more sensitive?



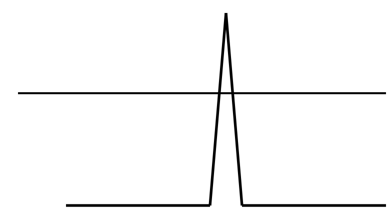
Programmed
Sensitivity 0.5 mV



OR

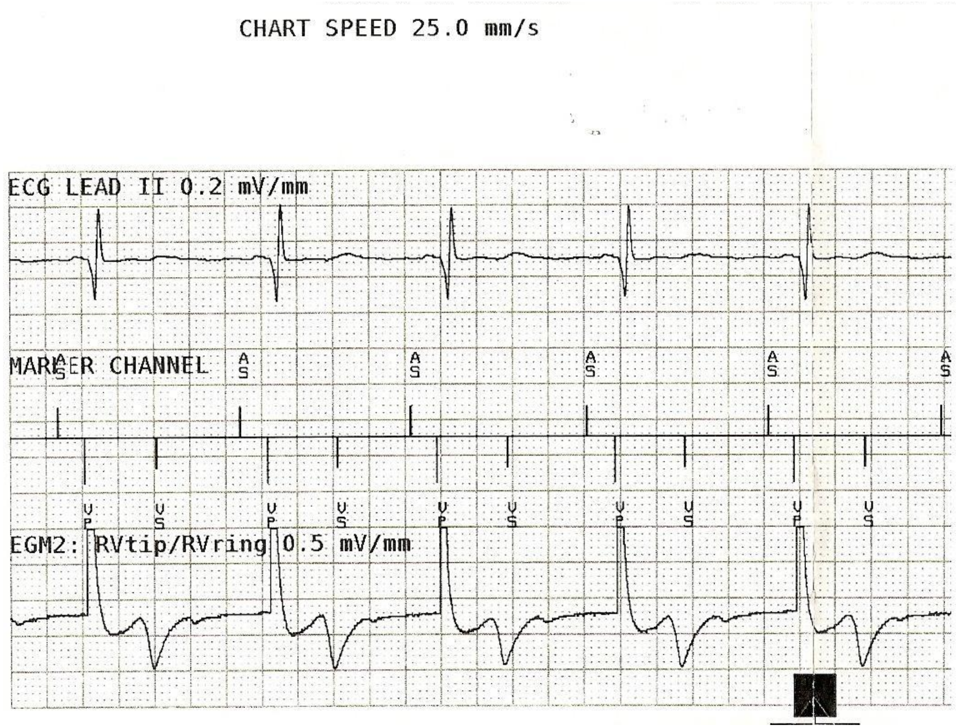


Programmed
Sensitivity 2.5 mV



Case Study: Telemetry Call

- You are on call and the telemetry nurse calls you because a patient's pacemaker is "malfunctioning."
- She saw that the lower rate was programmed to 60 but at times the patient is going 50 bpm.
- You grab the programmer and interrogate:

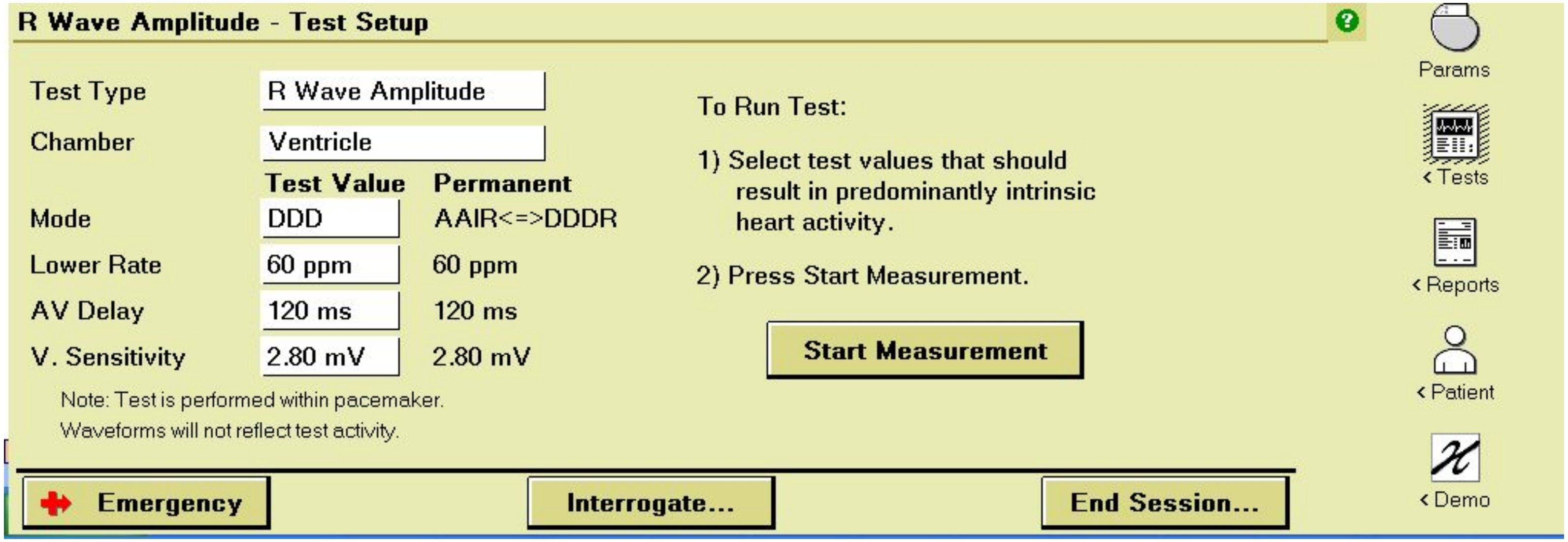


Solution

Now that we know what the problem is,

How do we fix it?

- Measure the size of the R waves
- Make the ventricular lead less sensitive by increasing the ventricular sensitivity



Key Learning Points

- The NBG code indicates the pacing mode and whether the pacemaker is pacing, sensing, and inhibiting in either the atrium and ventricle.
- There is a mathematical relationship between voltage, current, and resistance. These variables should be considered for patient safety (to ensure capture) and device longevity.
- Lead impedance is a key measure of lead integrity. Low or high impedance may indicate a faulty lead.
- Appropriate safety margins should be applied to the capture threshold to ensure patient safety.
- Proper sensing is vital to the operation of the pacemaker.

Brief Statement: IPGs and ICDs

Indications

- **Implantable Pulse Generators (IPGs)** are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and increases in activity and/or minute ventilation. Pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g. pacemaker syndrome) in the presence of persistent sinus rhythm.
- **Implantable cardioverter defibrillators (ICDs)** are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.
- **Cardiac Resynchronization Therapy (CRT)** ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration.
- **CRT IPGs** are indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration.

Brief Statement: IPGs and ICDs

Contraindications

- IPGs and CRT IPGs are contraindicated for dual chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competitive paced and intrinsic rhythms; unipolar pacing for patients with an implanted cardioverter defibrillator because it may cause unwanted delivery or inhibition of ICD therapy; and certain IPGs are contraindicated for use with epicardial leads and with abdominal implantation.
- ICDs and CRT ICDs are contraindicated in patients whose ventricular tachyarrhythmias may have transient or reversible causes, patients with incessant VT or VF, and for patients who have a unipolar pacemaker.

Warnings/Precautions

- Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transthoracic defibrillation paddles directly over the device. Additionally, for CRT ICDs and CRT IPGs, certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and / or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set.

Brief Statement: IPGs and ICDs

Potential Complications

- Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Brief Statement: Leads

Indications

- Medtronic leads are used as part of a cardiac rhythm disease management system. Leads are intended for pacing and sensing and/or defibrillation. Defibrillation leads have application for patients for whom implantable cardioverter defibrillation is indicated. The Attain Leads have application as part of a Medtronic biventricular pacing system.

Contraindications

Medtronic leads are contraindicated for the following:

- Ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve.
- Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate or dexamethasone acetate may be contraindicated. (includes all leads which contain these steroids).
- Epicardial leads should not be used on patients with a heavily infarcted or fibrotic myocardium.

The SelectSecure Model 3830 Lead is also contraindicated for the following:

- Patients for whom a single dose of 40.µg of beclomethasone dipropionate may be contraindicated.
- Patients with obstructed or inadequate vasculature for intravenous catheterization.

The Attain leads are contraindicated for patients with coronary venous vasculature that is inadequate for lead placement, as indicated by venogram. For the Model 4193 and 4194 leads, do not use steroid eluting leads in patients for whom a single dose of 1.0 mg dexamethasone sodium phosphate may be contraindicated

Brief Statement: Leads

Warnings/Precautions

- People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, or the need to reprogram or replace the device.
- For the SelectSecure Model 3830 lead, total patient exposure to beclomethasone 17,21-dipropionate should be considered when implanting multiple leads. No drug interactions with inhaled beclomethasone 17,21-dipropionate have been described. Drug interactions of beclomethasone 17,21-dipropionate with the Model 3830 lead have not been studied.
- Attain leads, stylets, and guidewires should be handled with great care at all times. When using a Model 4193 or 4194 lead, only use compatible stylets (stylets with downsized knobs and are 3 cm shorter than the lead length). Output pulses, especially from unipolar leads, may adversely affect device sensing capabilities. Back-up pacing should be readily available during implant. Use of leads may cause heart block. For the Model 4193 and 4194 leads, it has not been determined if the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate apply to the use of this highly localized, controlled-release device. For a list of potential adverse effects, refer to the Physician's Desk Reference. Patients should avoid diathermy. Previously implanted pulse generators, implantable cardioverter-defibrillators, and leads should generally be explanted.

Brief Statement: Leads

Potential Complications

- Potential complications related to the use of leads include, but are not limited to the following patient- related conditions: cardiac dissection, cardiac perforation, cardiac tamponade, coronary sinus dissection, death, endocarditis, erosion through the skin, extracardiac muscle or nerve stimulation, fibrillation or other arrhythmias, heart block, heart wall or vein wall rupture, hemoatoma/seroma, infection, myocardial irritability, myopotential sensing, pericardial effusion, epicardial or pericardial rub, pneumothorax, rejection phenomena, threshold elevation, thrombosis, thrombotic or air embolism, and valve damage. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation or exit block.
- See the specific device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic’s website at www.medtronic.com.
- Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Brief Statement: 2090 Programmer

<u>Intended Use</u>

The Medtronic CareLink programmer system is comprised of prescription devices indicated for use in the interrogation and programming of implantable medical devices. Prior to use, refer to the Programmer Reference Guide as well as the appropriate programmer software and implantable device technical manuals for more information related to specific implantable device models. Programming should be attempted only by appropriately trained personnel after careful study of the technical manual for the implantable device and after careful determination of appropriate parameter values based on the patient's condition and pacing system used. The Medtronic CareLink programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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