

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

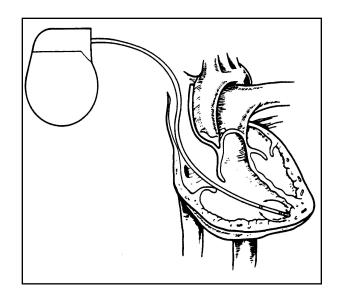
Objectives

- 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

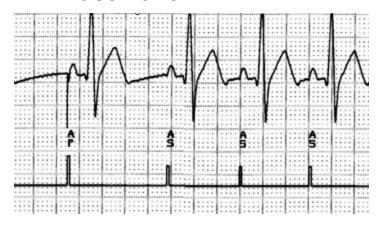
- One lead
 - Atrium
 - Ventricle (most common)
- May be used for patients in chronic AF (VVI pacemaker) or patients with sinus node dysfunction and no history of AV block (AAI pacemaker)



VVI Pacemaker



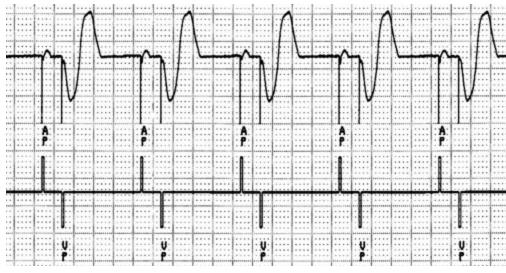
AAI Pacemaker

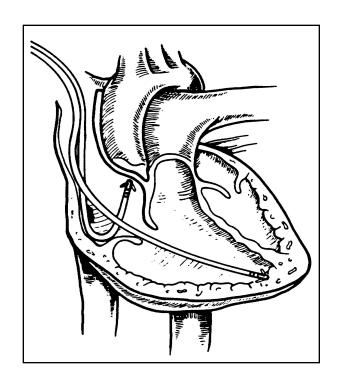


Dual Chamber System

- 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

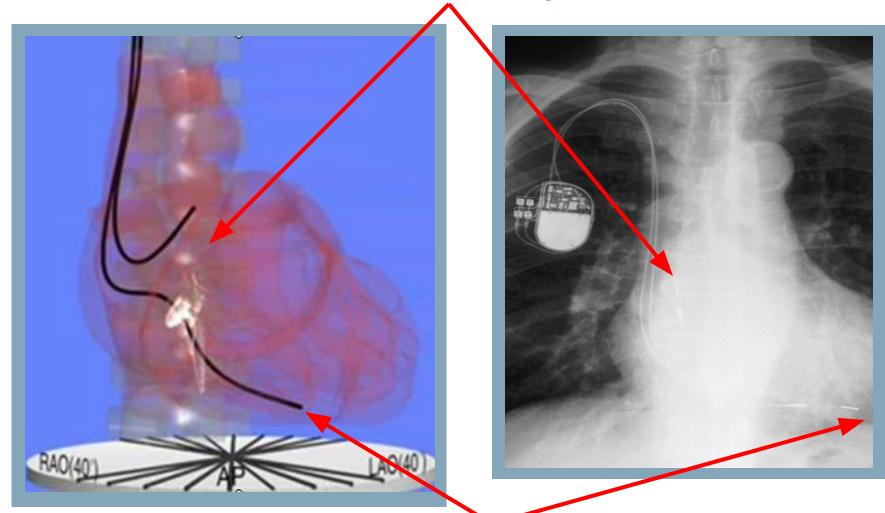






Dual Chamber Pacemaker

RA Lead in Appendage

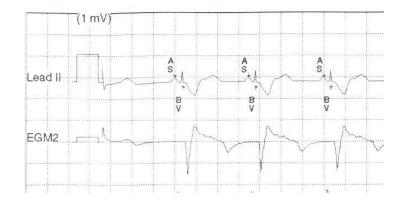


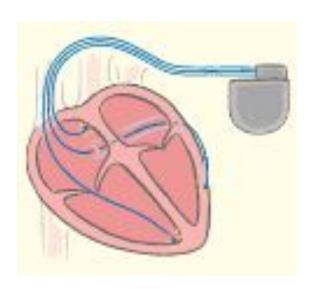
RV Lead at the Apex

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	O = None	O = None	O = None	O = None
A = Atrium	A = Atrium	T = Triggered	R = Rate	A = Atrium
V = Ventricle	V = Ventricle	I = Inhibited	modulation	V = Ventricle
D = Dual (A + V)	D = Dual (A + V)	D = Dual (T + I)		D = Dual (A + V)
S = Single (A or V)	S = Single (A or V)			

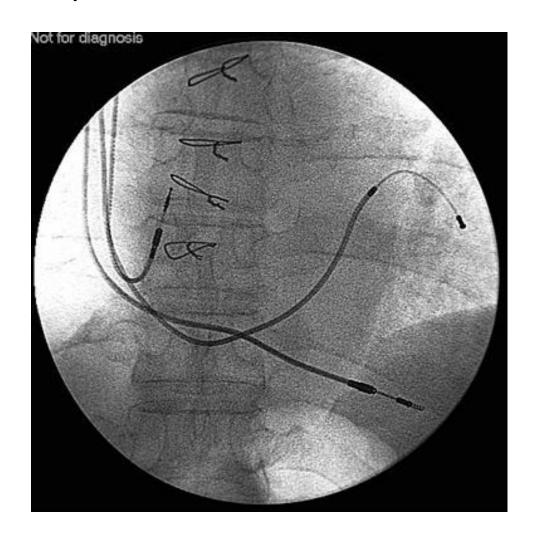
Examples of pacing modes which are typically programmed:

DDD VVI DDIR

DDDR VVIR AAIR

Knowledge Checkpoint

What type of pacemaker is this?



Knowledge Checkpoint

What does VVIR mode mean?

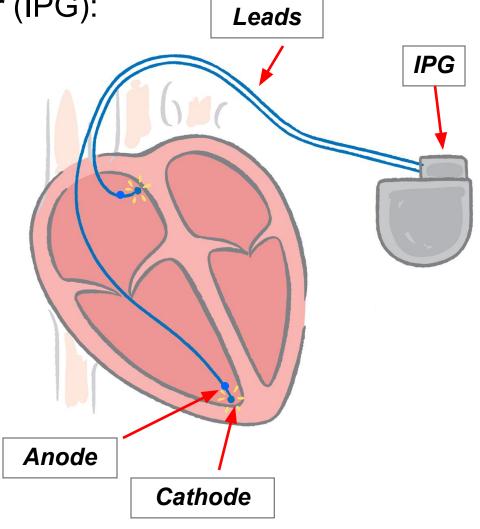
Key Learning Points

- 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

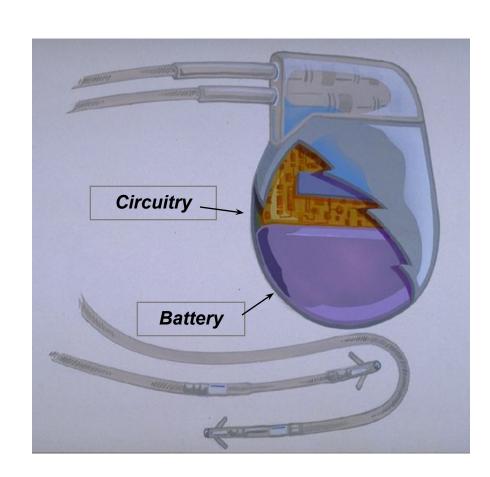
Implantable Pacemaker Circuit

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



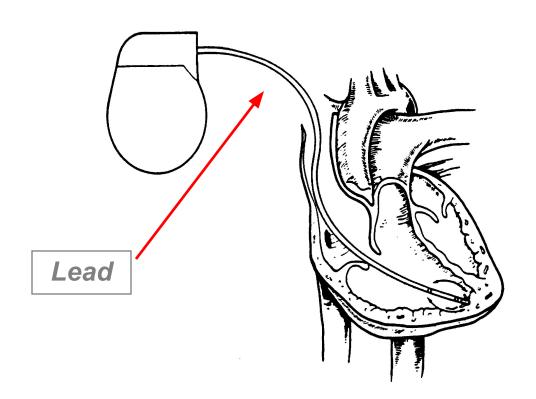
The Pulse Generator

- Lithium-liodine 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

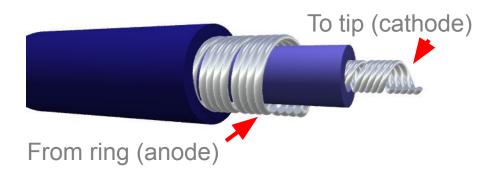
Unipolar leads

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



Bipolar leads

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

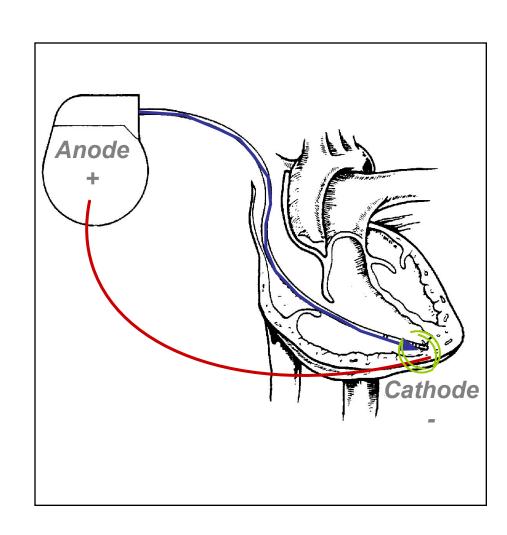


Bipolar coaxial lead

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

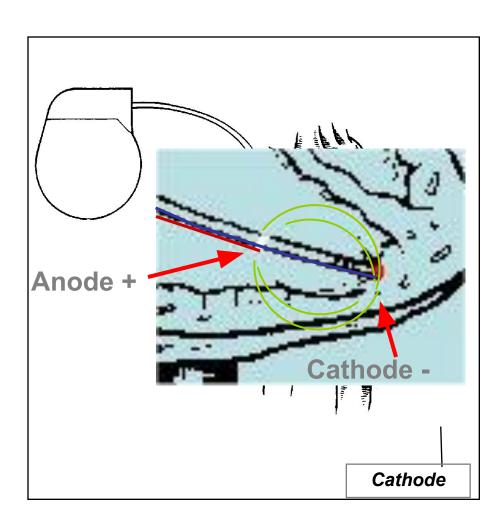
Unipolar Pacing System

- 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)

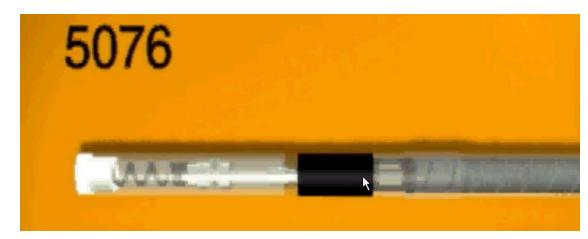
The tines become lodged in the trabeculae of the apex or the pectinate of the appendage which are fibrous meshworks of heart tissue



Active fixation (screw-in)

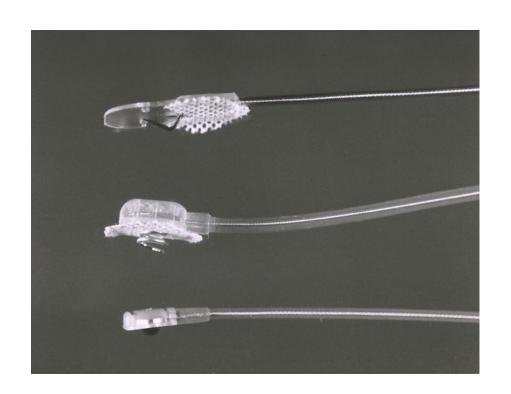
The helix, or screw, extends into the endocardial tissue

- 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



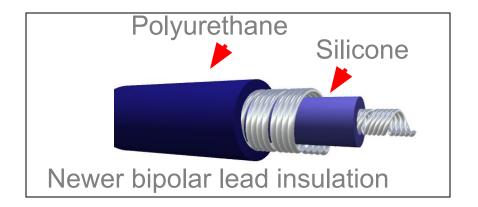
Lead Insulators

Silicone insulated leads

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

Polyurethane insulated leads

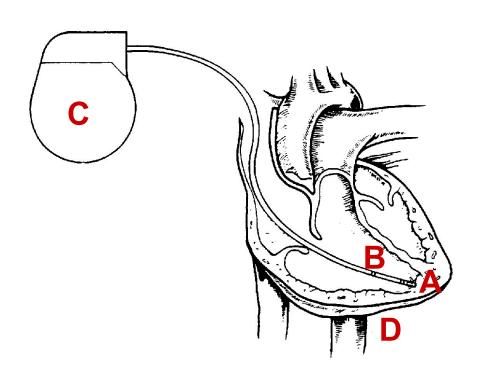
- Biocompatible
- High tear strength
- Low friction coefficient
- Smaller lead diameter



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

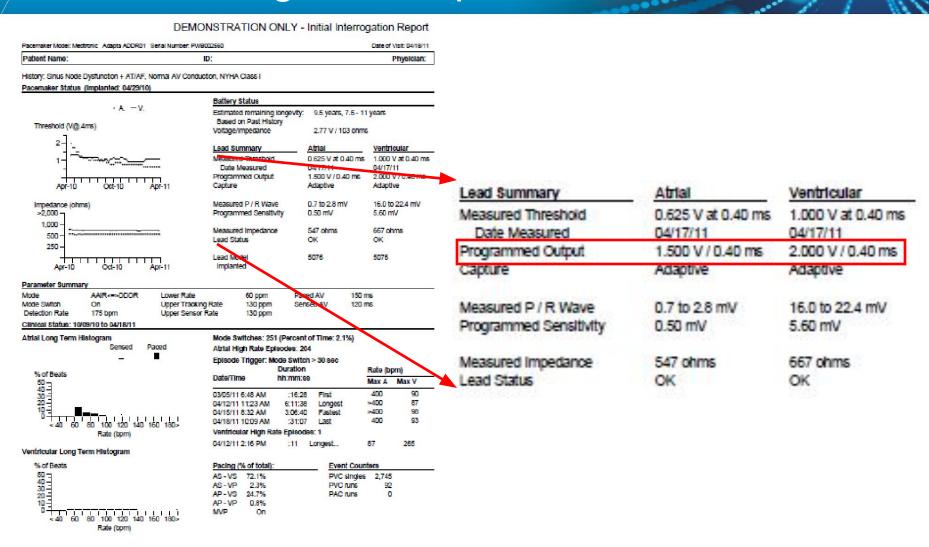
ELECTRICAL CONCEPTS IN PACEMAKERS

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

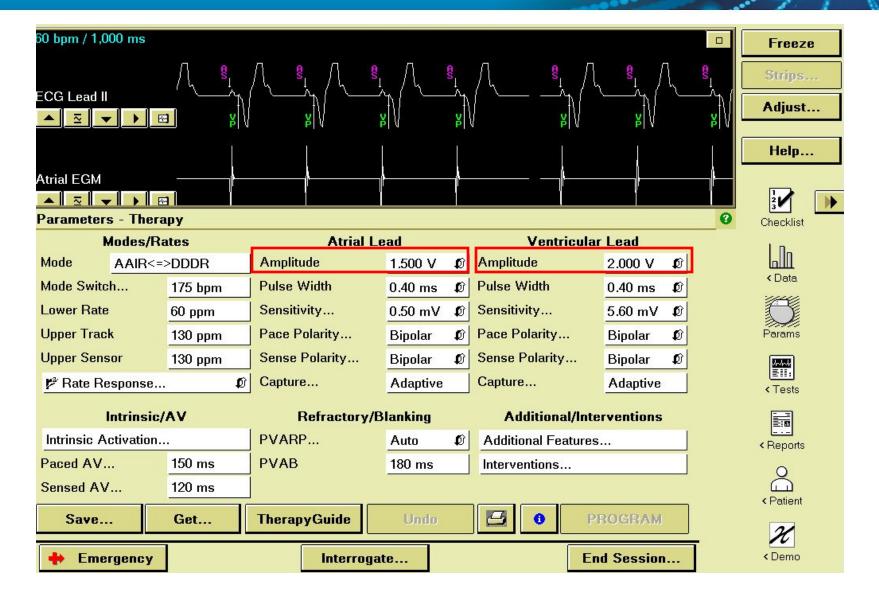
Note: The terms "amplitude" and "voltage" are often used interchangeably in pacing.

Initial Interrogation Report



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

Voltage

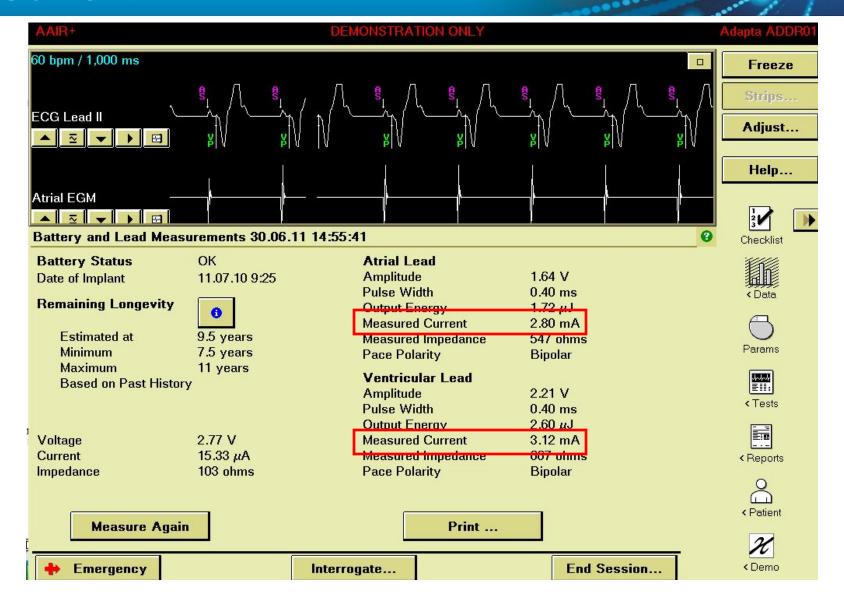


Current

- 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

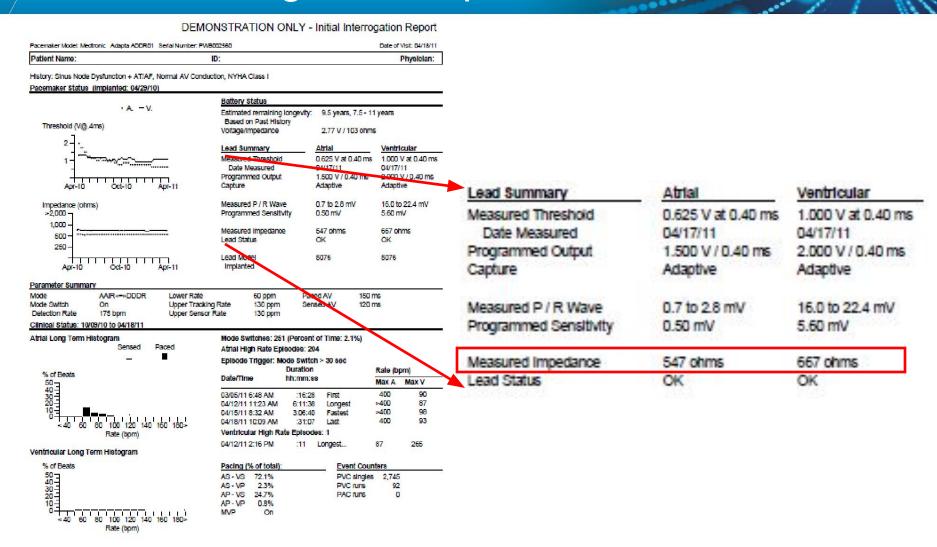
Current



Impedance

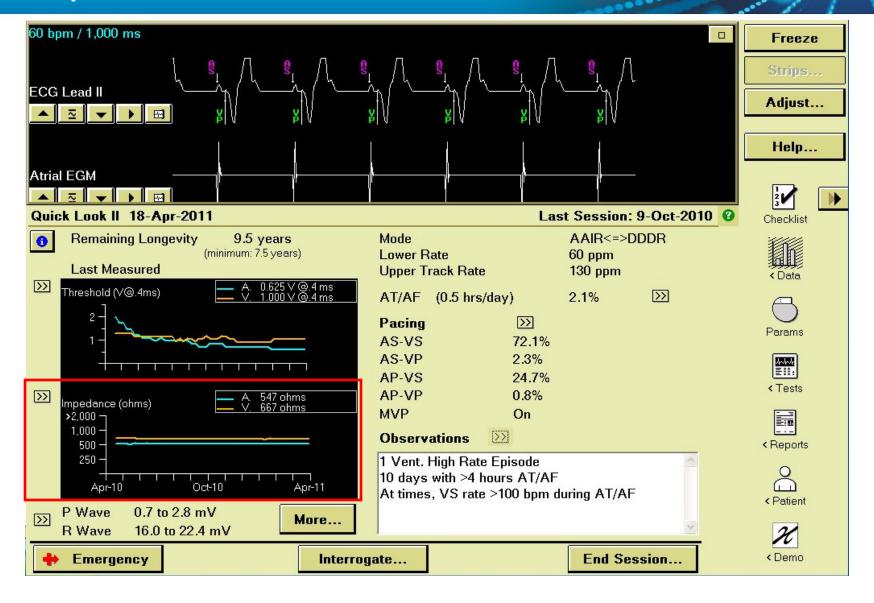
- The opposition to current flow
- In a pacing system, impedance is:
 - Measured in ohms (Ω)
 - Represented by the letter "R"
 - The sum of all resistances to the flow of current
 - Lead conductor resistance
 - The resistance to current flow from the electrode to the myocardium
 - Polarization impedance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

Initial Interrogation Report



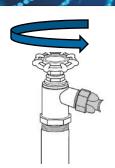
Note: All clinic, physician, and patient names and data in this document are fictitious

Impedance



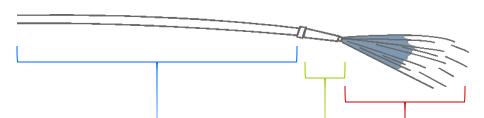
Summary Voltage, Current, and Impedance

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



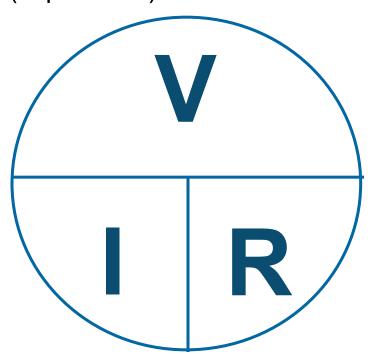
- Current: The actual continuing volume of flow of electricity (I)
 - This flow of electrons causes the myocardial cells to depolarize (to "beat")

- 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).

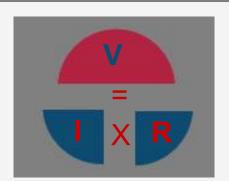


Ohm's Law

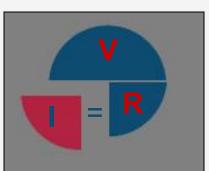
 Describes the relationship between voltage, current, and resistance (impedance)



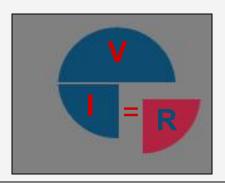
• V = I X R



• I = V / R



• R = V / I



Ohm's law tells us:

- 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

$$V = I \times R$$

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

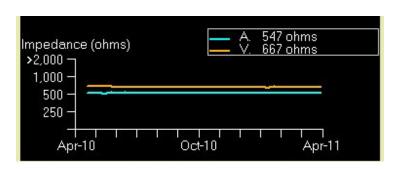
Key Learning Points

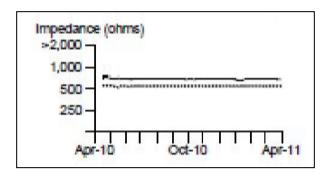
- Know where to find the voltage and impedance on the programmer and report
- Ohm's law and the relationship between voltage, current, and impedance
 - Knowing how these factors relate to each other can help you understand how the pacemaker paces the heart

TESTING THE PACEMAKER CIRCUIT

Typical Lead Impedance Range

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





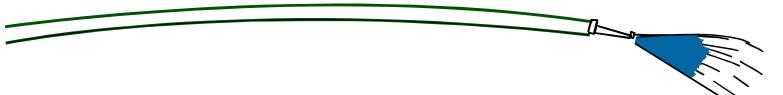
 Generally, a 30% change or abrupt change is something to be concerned about.

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

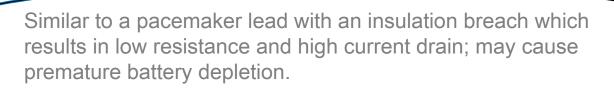
^{*}Impedance is higher for specially designed high impedance leads.

Lead Impedance Values Electrical Analogies

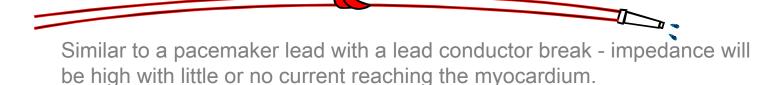
Normal resistance – friction caused by the hose and nozzle



Low resistance – leaks in the hose reduce the resistance



High resistance – a knot results in low total current flow



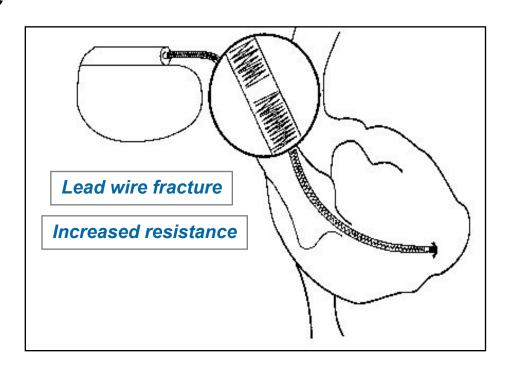
Knowledge Checkpoint

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)

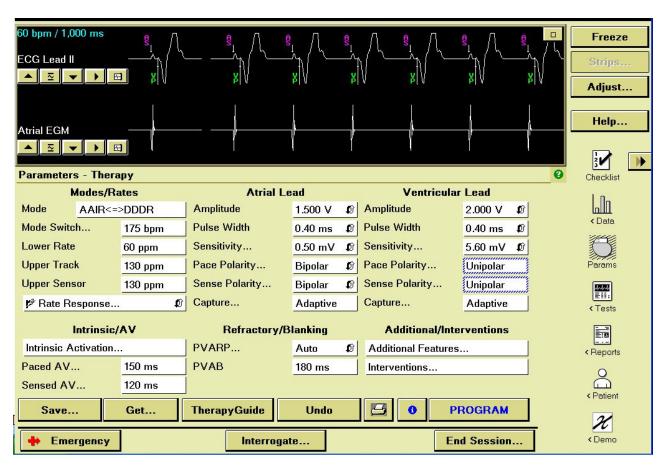
Lead Crush



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



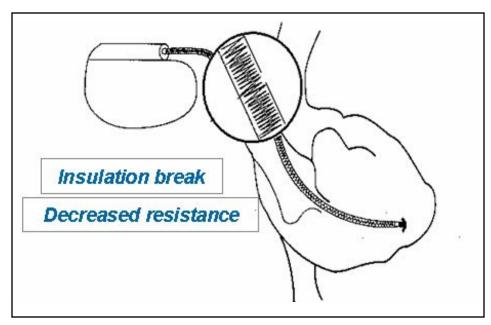
Knowledge Checkpoint

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

OK

Voltage 2.75 V Current 25.53 μA Impedance 100 ohms

Battery Status

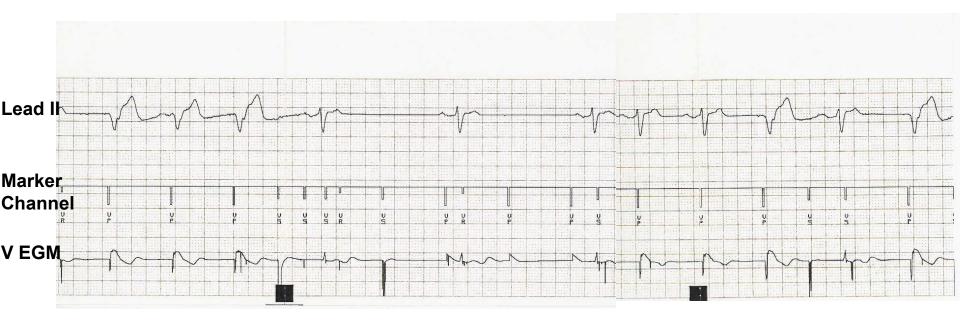
Remaining Longevity

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	$8.72\mu J$	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?

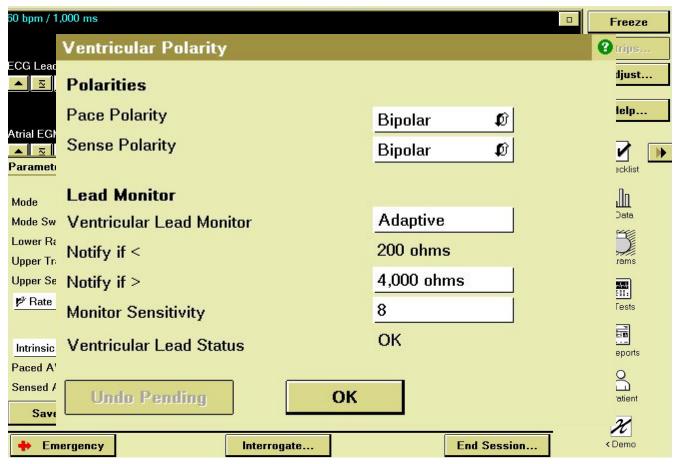
Insulation Break

- 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

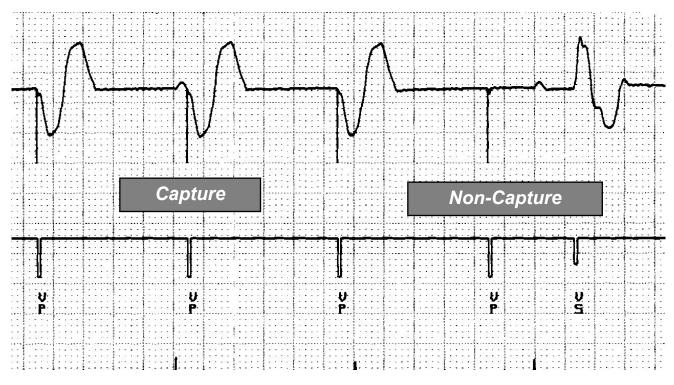


Replace the Lead

- •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

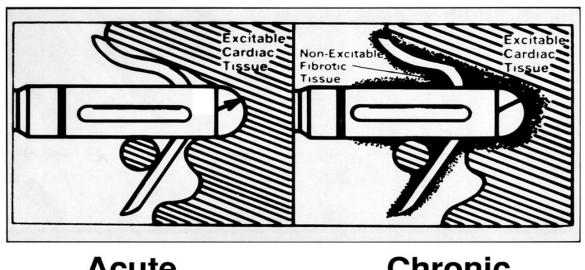


Ventricular pacemaker 60 ppm

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



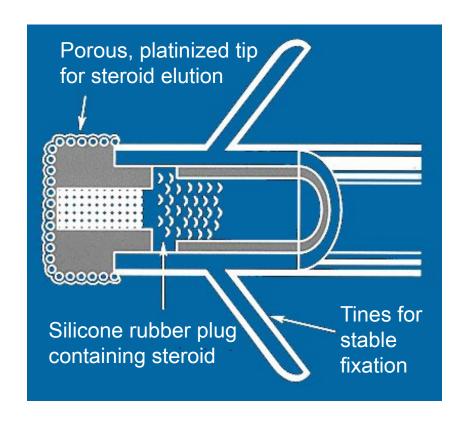
Acute

Chronic

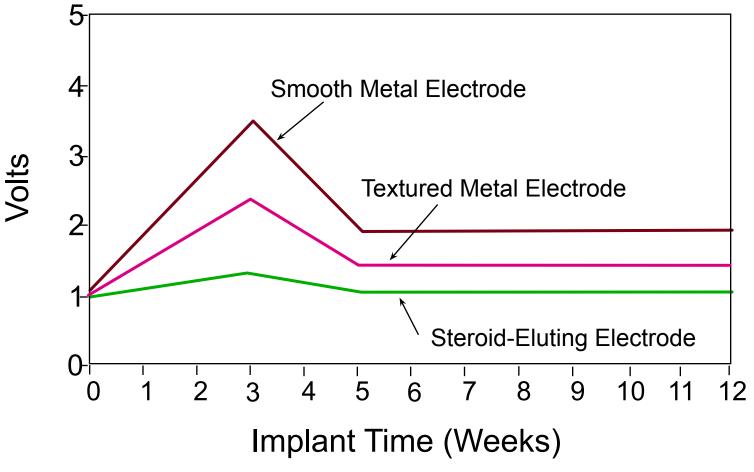
Ellenbogen, Kenneth A. and Mark A. Wood. (2005). Cardiac Pacing and ICDs. Massachusetts: Blackwell Publishing. (pg. 342).

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

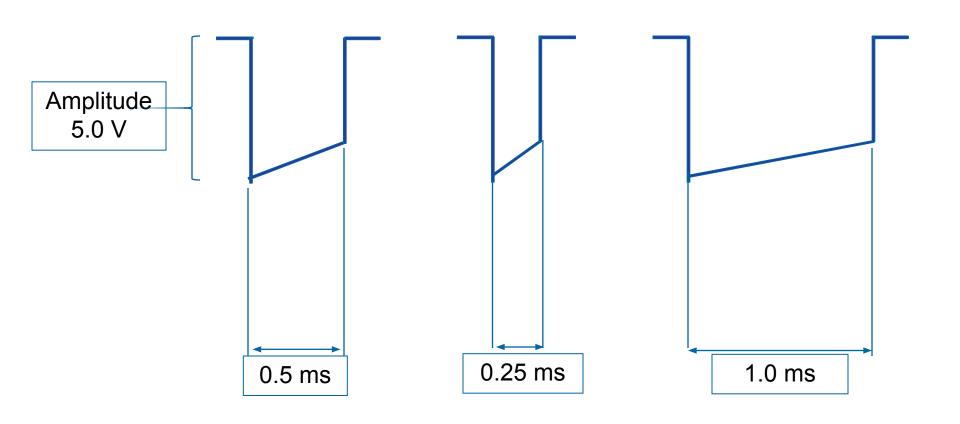
- Pacemaker circuit (lead) integrity
 - Insulation break
 - Wire fracture
- The characteristics of the electrode
- Electrode placement within the heart
- Drugs
- Electrolytes
- Sleeping/Eating

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

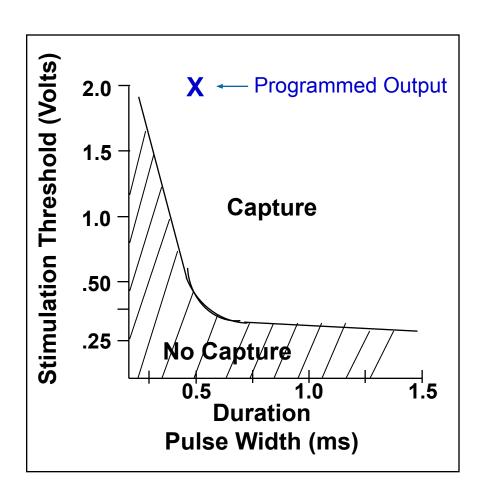
5.0 Volt Amplitude at Different Pulse Widths



Strength-Duration Curve

 Strength-duration curve shows relationship of amplitude and pulse width

 Adequate safety margins are important because thresholds can fluctuate slightly

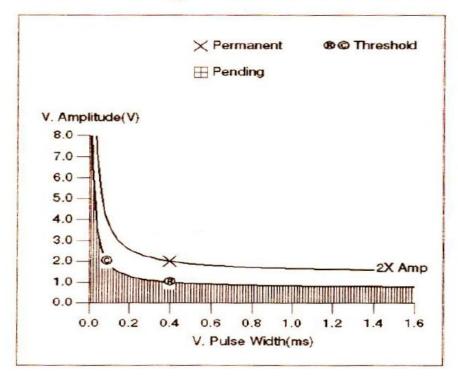


Strength Duration Curve Example

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

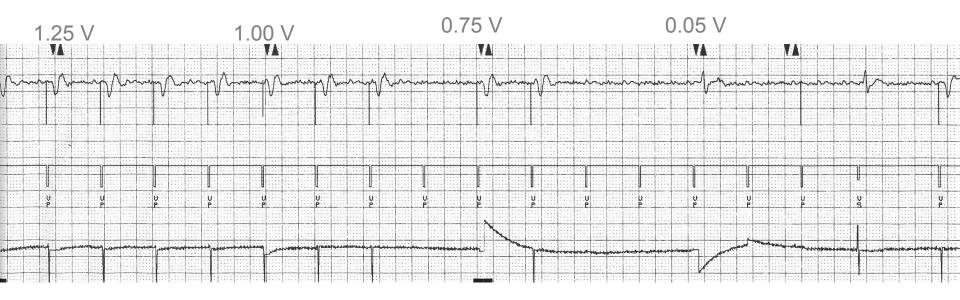
3 x Pulse Width Threshold

Programming Outputs

- Primary goal: Ensure patient safety and appropriate device performance
- Secondary goal: Extend the service life of the battery
 - Typically program amplitude to ≤ 2.5 V, but <u>always</u> 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

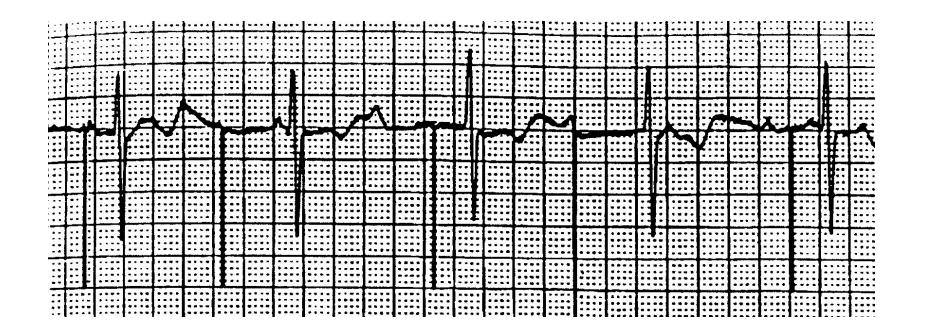
What is the threshold?



- 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?

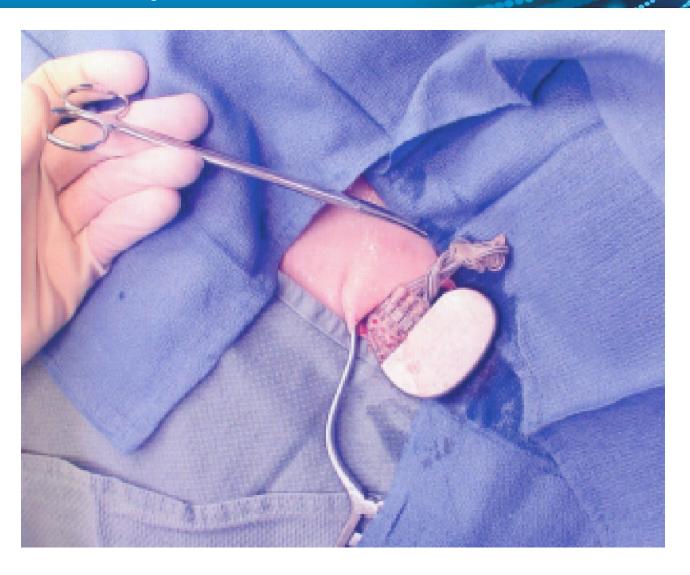


Order a Chest X-ray

The chest x-ray revealed a dislodged lead

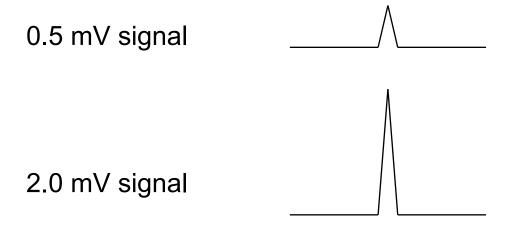


Twiddler's Syndrome



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



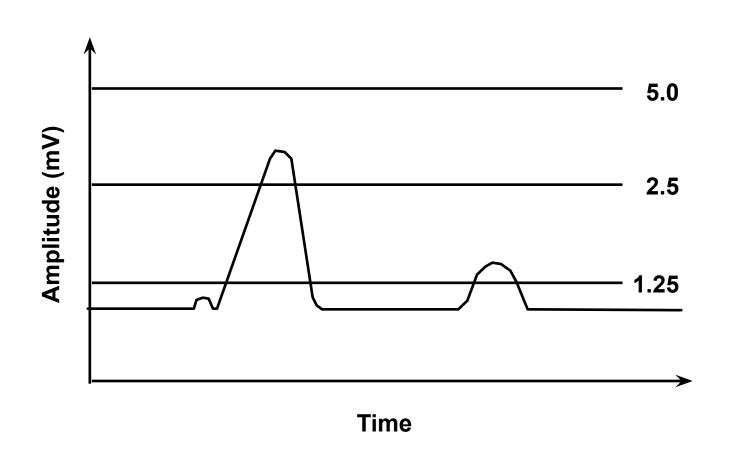
Sensing

Acceptable Sensing Values (mV)¹

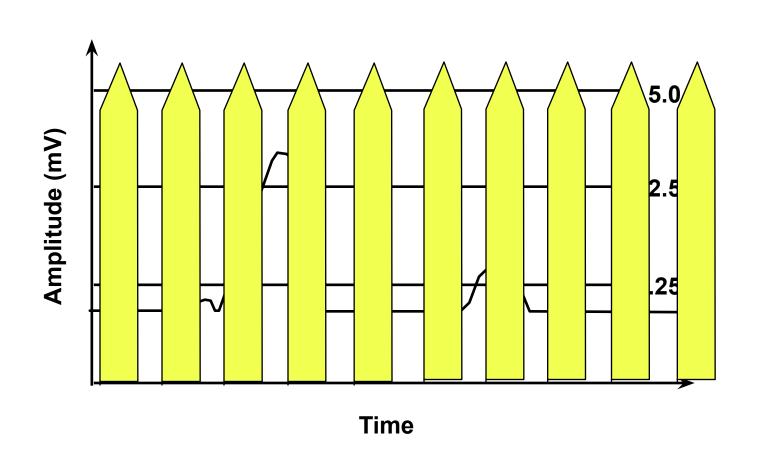
	Acute	Chronic
Atrium	>1.5	>1.0
Ventricle	>7.0	>5.0

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

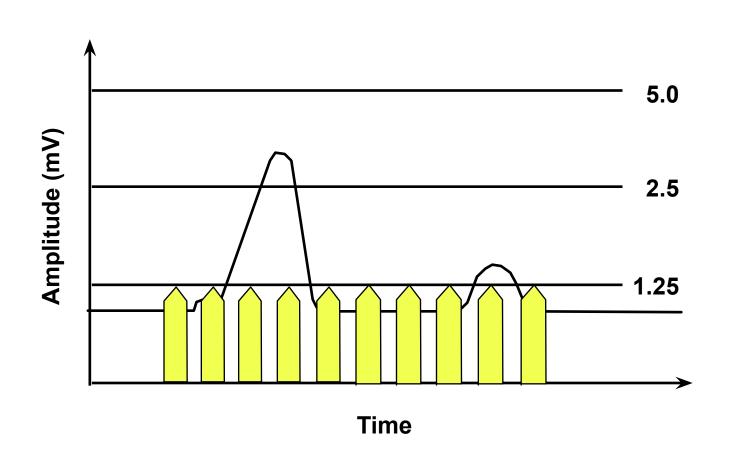
Sensitivity



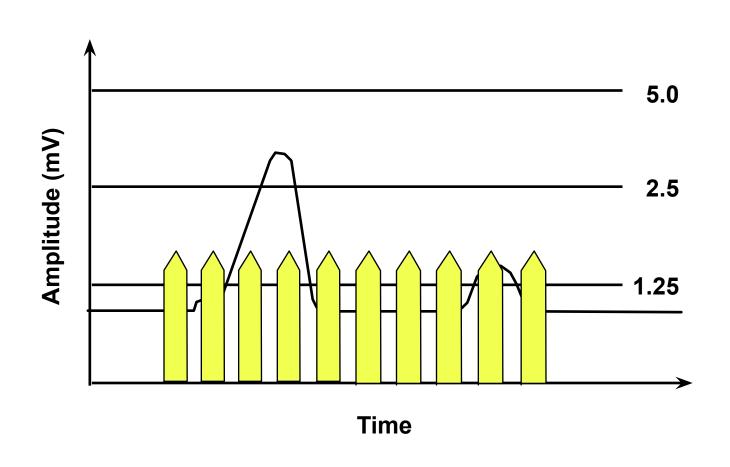
Less Sensitive = High Sensitivity Number



More Sensitive = Low Sensitivity Number



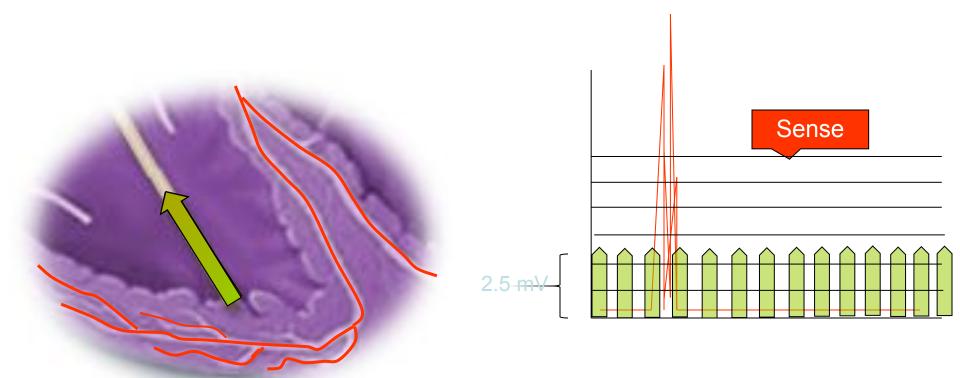
Adequate Sensitivity



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")

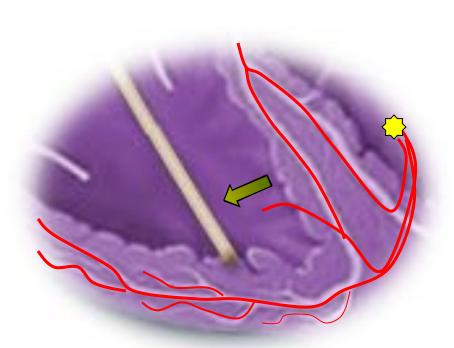
Vectors and Gradients



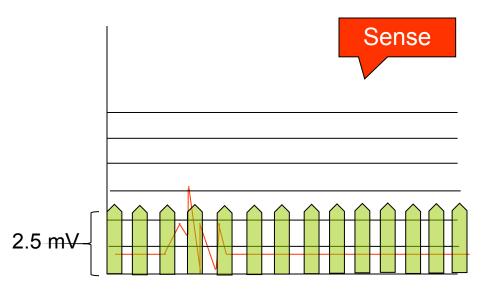
The wave of depolarization produced by normal conduction creates a gradient across the cathode and anode. This changing polarity creates the signal.

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?



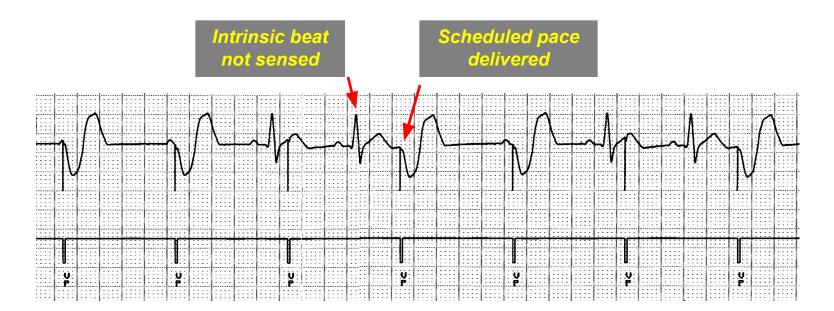
In this case, the wave of depolarization strikes the anode and cathode almost simultaneously. This will create a smaller gradient and thus, a smaller signal.

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

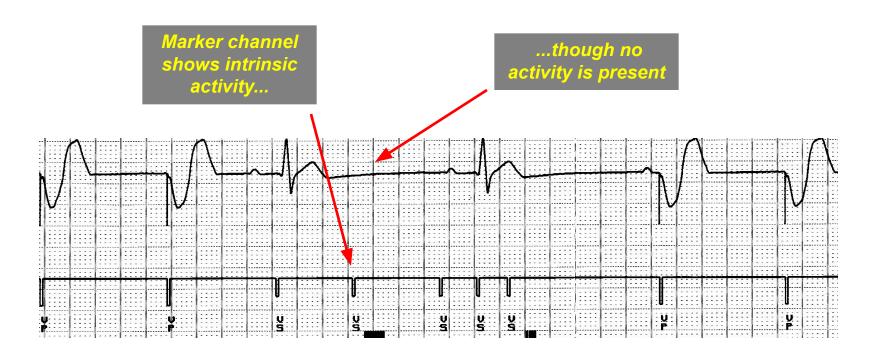
Undersensing . . . Overpacing

 Pacemaker does not "see" the intrinsic beat, and therefore does not respond appropriately



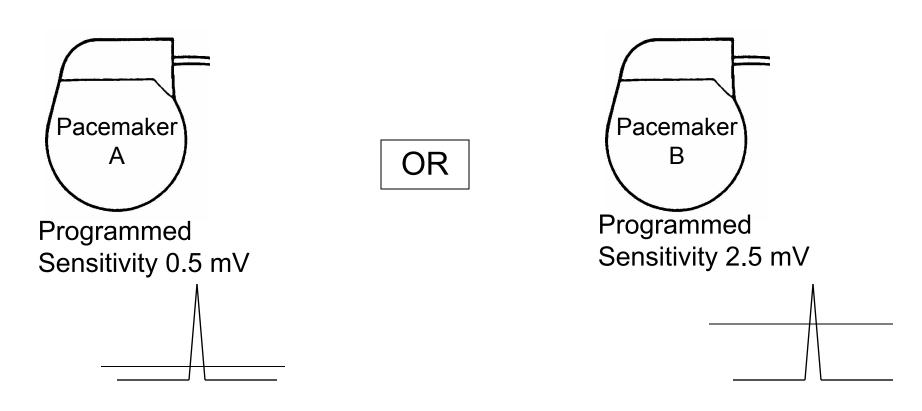
Oversensing ... Underpacing

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



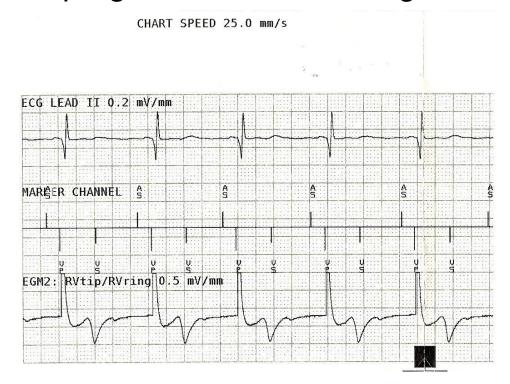
Knowledge Checkpoint

Which of these pacemakers is more sensitive?



Case Study: Telemetry Call

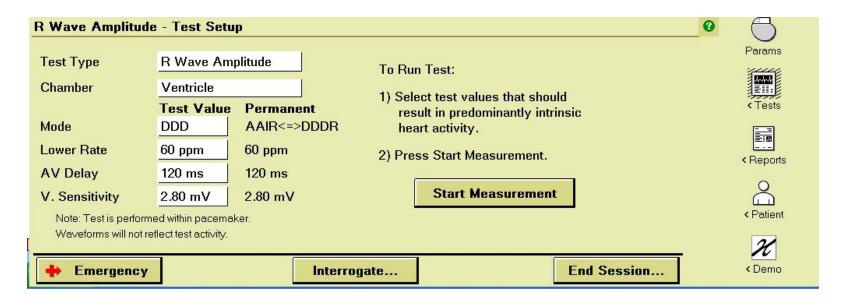
- You are on call and the telemetry nurse calls you because a patient's pacemaker is "malfunctioning."
- •She saw that the lower rate was programmed to 60 but at times the patient is going 50 bpm.
- •You grab the programmer and interrogate:



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

Intended Use

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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