

GUIDANT

USA HEADQUARTERS
GUIDANT CORPORATION CARDIAC RHYTHM MANAGEMENT
4100 HAMLIN AVENUE NORTH ST. PAUL, MN 55112-5798 USA
USA: 1 800 CARDIAC (227 3422) Worldwide: (1) (651) 582 4000
www.guidant.com

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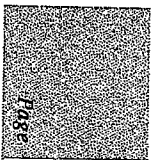


GUIDANT

THERAPY IN ACTION

MDC Patient Handbook

CPI 34 00000001



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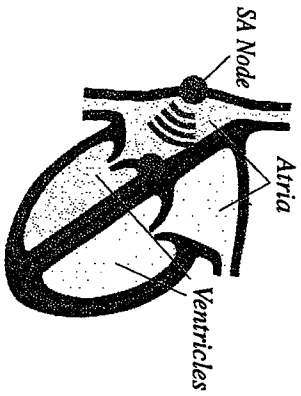
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UNDERSTANDING YOUR CONDITION

Introduction

Your doctor has recommended a Guidant automatic implantable cardioverter defibrillator (AICD) system to treat your rapid heart rhythm. Guidant AICD systems have been used successfully for over fourteen years in more than 140,000 people. Consult your physician about any potential risks or adverse events associated with your implanted AICD.

This booklet will tell you how an AICD system senses and treats heart rhythms that are too fast. It discusses activities that you can begin and those you should avoid doing after your surgery. It talks about some of the changes that may occur in your life. It will also answer many questions that AICD patients typically have. If you have more questions after reading this material, ask your doctor.



Your heart's natural pacemaker

Your heart is able to beat because it produces electrical impulses. These impulses travel through the heart muscle and stimulate it to contract, or beat.

Normally, these impulses come from a small area in your heart called the sinoatrial (SA) node. This area is located in the upper right chamber, or right atrium. When the SA node signals the two upper chambers of the

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heart, the atria, they contract at the same time. This causes blood to finish filling the two lower chambers, the ventricles. The impulse then travels to the ventricles causing them to contract. This produces a heartbeat. After a brief rest, the cycle begins again.

Sometimes things go wrong in the heart's electrical system causing an abnormal, often irregular heartbeat called an arrhythmia. Arrhythmias may prevent the heart from pumping enough blood throughout your body.

Ventricular Tachycardia If your heart's electrical signals come from an area in one of the ventricles (instead of the SA node), the arrhythmia is called ventricular tachycardia (VT). The electrical signal does not run through the heart normally, and the heart may not contract normally. The fast heart rate might feel as though the heart is skipping beats.

As the heart beats faster, it pumps less blood. There is not enough time for the heart to fill with blood between beats. If this rapid heartbeat continues, the brain and body may not receive enough blood and oxygen. If your brain needs more oxygen-carrying blood, you may experience fainting

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spells, blackouts, temporary blind spots, dizziness and, eventually, unconsciousness and cardiac (heart) arrest.

Ventricular Fibrillation Instead of an abnormal electrical impulse starting from one spot in the ventricles (as in VT), ventricular fibrillation (VF) commonly involves many different spots in the ventricles trying to signal the heart to beat. The heartbeat is much faster than normal, sometimes over 300 beats a minute. Very little blood is pumped from the heart to the rest of the body. If your heart is in VF, you can become unconscious very quickly. You might not remember anything that happened just before or during the episode.

Extremely fast and irregular ventricular arrhythmias can be treated with electrical devices, such as the external defibrillators carried by paramedics or an AICD. The defibrillator produces an electrical shock that passes through the heart. The shock stops the abnormal signals and allows the SA node to return the heart to a more normal rhythm.

If an episode of VT or VF continues without treatment, the heart cannot supply enough oxygen-carrying blood to the brain and body tissues.

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Without oxygen, the brain and body tissues cannot function normally and will die.

Bradycardia Sometimes the heart beats too slowly. This can be caused by the SA node not working properly or by a condition called heart block. Heart block exists when there is a problem with the electrical pathway between the upper and lower chambers of the heart. The natural pacemaker signals sent out by the SA node might be delayed or might fail to reach the ventricles altogether.

During bradycardia, the chambers of the heart do not contract often enough to supply the proper amount of blood to your body. A person with bradycardia can frequently feel tired or could faint.

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YOUR AICD SYSTEM.

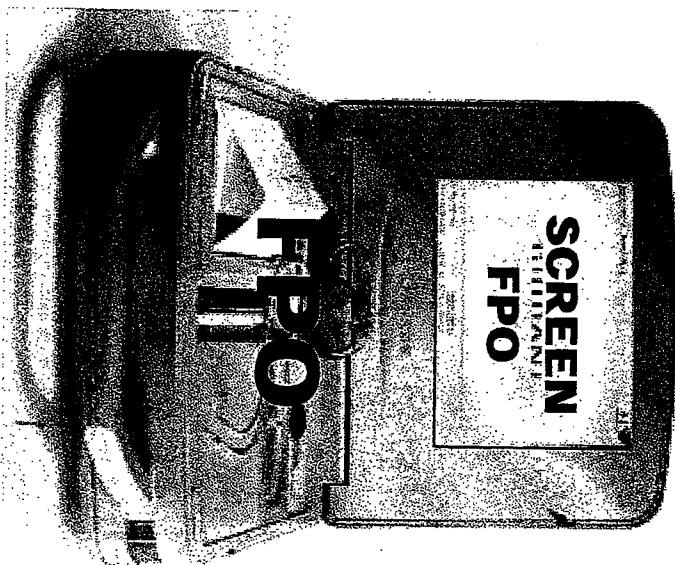
What is the AICD system?

The AICD system includes a pulse generator and one or more leads that are implanted in your body. A programmer is used in the hospital or your doctor's office to change the settings in the pulse generator.¹

The Pulse Generator The pulse generator is like a small computer that runs on a battery. It can monitor your heart's electrical function and tell the device to deliver electrical energy when it senses an arrhythmia.

Based on the settings your doctor has programmed, the pulse generator will deliver one or more therapies to treat ventricular arrhythmias. The memory in the device stores therapy and device information that

¹ A variety of Guidant AICD systems are available to treat cardiac arrhythmias. Not all devices have the same settings, features or capabilities.



Your doctor retrieves during follow-up visits. Your AICD device stores a picture of your arrhythmia and the treatment the device used to correct it. This allows your doctor to better evaluate your heart rhythms. Your doctor can also determine if the programmed treatment is successful. This information allows your doctor to change the device settings if your heart condition changes.

The Lead System The leads are insulated wires that carry the heart signal to the pulse generator. They also carry energy from the pulse generator to the heart. One end of each lead connects to the AICD pulse generator. The other is placed in the heart or under the skin near the heart. Depending on the type of AICD, one or more leads may be used.

The Programmer The programmer communicates with the AICD system via radio frequency signals through a telemetry wand. It works much like the remote control for changing channels on a television set. The doctor uses the programmer to program and test the AICD device after it is implanted and right before you leave the hospital. During the follow-up

exam, the programmer collects information stored in the pulse generator's memory since your last visit.

How your AICD system works

The AICD system watches your heart all the time, waiting for an arrhythmia to occur. If one is sensed, the AICD automatically determines what type of treatment, if any, you need and delivers it.

Antiarrhythmia pacing, cardioversion or defibrillation are used for treatment depending on the rhythm seen by the device. When the AICD system sees a rhythm that is faster, slower or different from your normal rhythm, it checks to see if the rhythm should be treated. Based on the settings programmed by your doctor, the device will deliver its therapy.² This may take from a few seconds to a few minutes. The amount of time depends on the type of rhythm sensed and how it compares to the programmed settings. Your doctor will let you know what therapy will be delivered by your AICD system.

² The therapy delivered also depends on the type of device you have and your specific arrhythmia.

How therapy feels when it is delivered

- **Antiarrhythmia Pacing** If your arrhythmia is regular but fast, the AICD system can deliver a series of small, rapid electrical pacing pulses. These are used to interrupt the arrhythmia and return your heart to its normal rhythm. You may not feel pacing therapy when it is delivered to your heart, or you may have a feeling of fluttering in your chest. Most patients who receive pacing therapy say it is painless.
- **Cardioversion** If your arrhythmia is regular but very fast, the AICD system can deliver a low-energy shock. This can stop the arrhythmia and return your heart to its normal rhythm. These low-energy shocks are stronger than pacing pulses. Many patients say cardioversion is mildly uncomfortable, like a thump on the chest.
- **Defibrillation** For arrhythmias that are very fast and irregular, high-energy shocks can be used to stop the arrhythmia. Then your heart can return to its normal rhythm. Many patients faint or become unconscious shortly after a very fast VT or VF rhythm starts. As a result, they do not feel these high-energy shocks. Of those patients who are conscious,

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some describe the shock like a "kick in the chest." Usually, the shock comes suddenly, and the sensation lasts for only a second. While many find the shock reassuring, other patients may be upset for a short time after the shock is delivered.

- **Bradycardia Pacing** Most AICD systems can sense and pace one chamber of your heart at a normal rate. Some AICD systems will sense and pace two chambers in your heart.

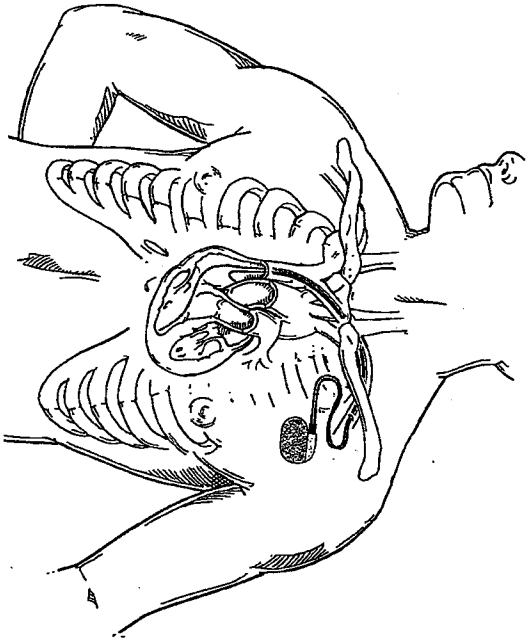
For many patients, the natural electrical signals in the heart are too slow. In addition, the electrical pathway to the lower heart can be partly or completely blocked. Pacing can restore the heart's normal rhythm.

Some AICD devices can be programmed to change their pacing rate up or down as your level of physical activity changes.

These "adaptive-rate" devices use a special sensor in the pulse generator to detect changes in your activity level. These pacing pulses are very low energy and are typically not felt by patients. If you have an AICD system that adapts the pacing rate to activity, you may be able to feel the increase in rate as you increase your level of physical activity.

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Implanting your AICD system

Implants require about one hour of surgery in most cases. For most cases, the doctor will introduce the lead into a vein, usually through a small cut

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near your collarbone. The doctor can then pass the lead through the vein and position it inside your heart. The tip of the lead (an electrode) rests directly against the inner heart wall.

Some patients may require an additional lead. These leads can be placed just under the skin next to your rib cage through a small incision on your left side.

If your doctor determined your heart condition requires two-chamber pacing treatment, one of the leads you have is positioned in the upper right chamber (atrium) of your heart and one is positioned in the lower (ventricle) chamber.

During the operation, the AICD system will be tested to make sure it is working properly. During this test, your doctor will start an arrhythmia in your heart and allow the device to sense the rhythm and give the programmed treatment. Sometimes after implant, another test that may be performed is an exercise treadmill test. This test helps your doctor watch your heart rhythm and know how your AICD system is working.

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GOING HOME

What to expect

As you recover from surgery and go home, you will find that the AICD system will allow you to return to an active lifestyle assuming you follow these guidelines.

After surgery

Your recovery from surgery might be slow and can take from several days or weeks to a few months. It is important that you become actively involved in your own recovery by following your doctor's instructions, including:

- Report any redness, swelling or drainage from your incisions.
- Avoid lifting heavy objects until your doctor says you may.
- Walk, exercise and bathe according to your doctor's instructions.
- Don't wear tight clothing that could irritate the skin over the pulse generator.

- If directed by your doctor, limit arm movements that could affect the lead system.
- Avoid contact sports that could result in blows to your implant site.
- Tell your other doctors, dentists and emergency personnel that you have an AICD device.

Activities and exercise

Your doctor will help you decide how soon you can resume your normal activities without fear of harming yourself or your AICD system. Such activities may include:

- Returning to your job
- Traveling
- Resuming sexual intimacy
- Pursuing hobbies

Depending on your condition, your doctor might ask you to avoid activities during which a few seconds of unconsciousness could be dangerous to you or others. These activities include driving, swimming or boating alone, or climbing a ladder.

Driving

Driving laws and the symptoms caused by your arrhythmia are often the deciding factors in whether or not you will be allowed to drive. Your doctor will advise you on what is best for your safety and the safety of others.

AICD patient identification card

Always carry your AICD identification to alert medical and security personnel that you have an implanted device.

Your AICD patient identification card contains your name, address, phone number, doctor's name and phone number, and the model numbers of your leads and pulse generator. It also contains important instructions for emergency personnel, should you need treatment.

If you move or if you select a new doctor, tell your doctor that you need a new AICD patient ID card.

Planning a trip

Be sure to check with your doctor before planning a trip away from home. In addition:

- Contact your doctor for instructions on who to call in an emergency.
- Show your AICD security card to airport security. (Look for the Airport Security and Things to Avoid sections in this booklet.)
- If you are going away for several months, ask your doctor for the name of a doctor you can see for a follow-up visit.
- Take this patient booklet along for reference.
- Ask your doctor what you should do if you receive therapy.

IMPORTANT FACTS ABOUT YOUR AICD SYSTEM

Operating household appliances and tools

The AICD device has built-in features that protect it from interference produced by most electrical appliances. You can continue to safely operate most appliances and tools that are properly grounded and in good repair, including the following:

- Microwave ovens
- Televisions, AM/FM radios, VCRs
- Tabletop appliances such as toasters, blenders, electric knives and can openers
- Handheld items such as shavers and hair dryers
- Electric blankets and heating pads
- Major appliances including washers, dryers and electric stoves

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- Spark-ignited internal combustion engines such as lawn mowers and leaf-blowers
- Electric typewriters and copying machines
- Personal computers
- Machine shop tools such as drills and table saws

Things to avoid

Most of the things you handle or work around on a daily basis are not going to influence the AICD system. However, your device is sensitive to strong electrical or magnetic fields. Keep the following potential sources of strong electrical or magnetic fields at least 30 cm (12 inches) away from your AICD pulse generator:

- Stereo speakers that are in large stereo systems, transistor radios, "boom boxes," etc.
- Strong magnets
- Magnetic wands used by airport security, "Bingo" games, etc.
- Industrial equipment such as power generators, arc welders and motors
- Battery-powered cordless power tools such as screwdrivers, drills, etc.

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You should also avoid leaning over any electric motor that is running, such as the alternator of an automobile. These frequently contain magnets. Also avoid standing near anti-theft devices in doorways of department stores and public libraries. You may walk through them at a normal pace.

Check with your physician about using radio frequency, remote-controlled transmitters used for toy cars and airplanes. These devices may affect some AICD pulse generators.

Your device may make sounds if you are too close to a magnet. The device may beep (about once per second) or make a continuous tone. Move away from the object or location immediately and call your doctor.

Cellular Phones

In certain cases, a cellular phone could affect your AICD system's operation if it is closer than 15 cm to the pulse generator. To reduce the chance of any interaction, follow these precautions:

- Maintain a distance of at least 15 cm (6 inches) between the cellular phone and your AICD pulse generator. If the phone transmits more than 3 watts, increase the distance to 30 cm (12 inches).

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- Hold the cellular phone on the opposite side of your body from your AICD pulse generator.

- Don't carry a cellular phone in a breast pocket or on a belt if that places the phone within 15 cm (6 inches) of your AICD pulse generator.

These precautions apply only to cellular phones, not to household cordless phones. However, you should avoid placing your household cordless phone receiver directly over your AICD pulse generator.

If you have questions about any situation or piece of equipment, contact your doctor.

Airport security

The security archway will not harm your AICD. However, the handheld wand used by airport security personnel could turn off your device if held over it for a period of time. You should show your AICD identification card and your AICD security card (available from your doctor) to the security personnel. A search with a wand should be avoided. Ask to be hand searched in place of a handheld wand. If the wand must be used, you should sit still. Ask security personnel that the search must be done quickly. Tell them

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not to hold the wand over your device. If you have any questions regarding airport security, contact your doctor.

Dental and medical procedures

Tell all medical personnel that you have an AICD. A few medical procedures might affect the AICD system. Magnetic resonance imaging (MRI) is a diagnostic test that uses a strong electromagnetic field and should be avoided. Hospitals keep MRI equipment in rooms marked with signs that indicate that magnets are inside. Do not go inside these rooms. Diathermy uses an electrical field to apply heat to tissues in the body and should be avoided. Electrocautery, used during surgical procedures to stop blood vessels from bleeding, should be used only when your device is turned off. Dental drills and cleaning equipment will not interfere with your AICD device. If it is medically necessary to undergo any surgical procedures, tell your dentist and/or doctor that you have an AICD system. They should then contact your heart doctor to find the best way to provide treatment.

The workplace

If you have any questions about your work environment, your doctor can start procedures to evaluate whether your job is likely to affect your AICD device.

LIVING WITH YOUR AICD SYSTEM

Your responsibility

You must follow your doctor's instructions and keep follow-up appointments. You should do the following:

- Ask your doctor any questions you may have about your AICD system.
- Take the medications prescribed for you, as instructed by your doctor.
- Carry your AICD identification cards with you at all times.
- Tell your family doctor, dentist and emergency personnel that you have an AICD.

When to call the doctor

Your doctor will provide guidelines for when you should contact him or her. In general, phone your heart doctor if you:

- Receive any therapy from your device and have been instructed to call.

- Have symptoms of an abnormal heart rhythm and have been instructed to call.
- Notice any swelling, redness or drainage from your incisions.
- Develop a fever that does not go away in two or three days.
- Have questions about your AICD device, heart rhythm or medications.
- Plan to travel or move.
- Hear any beeping sounds coming from the device.
- Notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you had before you received the device.

What to do if you receive a shock

Use the space in the back of this booklet to write down telephone numbers and information about your current medications. Keep this information near your phone.

If you have symptoms of a fast heart rate, it is likely that the AICD system will deliver therapy within a few seconds. There usually isn't much time to react. What should you do?

1. Remain calm and find a place to sit or lie down.
2. If possible, have someone who is prepared to provide you CPR, if you should need it, stay with you throughout the event.
3. Have a friend or family member be alerted to phone for an ambulance if you remain unconscious for more than one minute.
4. If you are conscious but do not feel well after the shock, have someone call your doctor. Follow your doctor's orders carefully.
5. If you feel fine after the therapy and no more symptoms appear, it may not be necessary to seek medical help immediately; however, follow your doctor's instructions for when to call his or her office. For example, if the shock occurs at night, your doctor may tell you to call the next morning. Someone at the doctor's office will ask you questions such as:

What were you doing right before the shock?

What symptoms did you notice before the shock?

At what time did the shock occur?

How did you feel right after the shock?

Symptoms without shocks It is possible that you could feel symptoms yet not receive therapy. This depends on the programmed settings of your AICD device. Sometimes exercise may cause shortness of breath, dizziness or lightheadedness. At other times, an abnormal heart rhythm may cause symptoms, but it may not be fast enough for your AICD device to deliver therapy. In either case, if symptoms are severe or continue for more than a minute or so, you should seek immediate medical attention.

Follow-up visits

Follow-up visits allow your doctor to check that your device is working properly. Your doctor can also check whether the drugs you might be taking affect how well your AICD system works. Because your heart condition may change over time, your doctor needs to be aware of these changes.

Your doctor will schedule regular device check-ups every two to three months. A typical follow-up visit lasts about 20 minutes. During these sessions, several tests may be done, including:

- Printing out information on how your AICD system performed since your last visit.

- Adjusting the programmed settings of your device, if necessary
- Checking the battery to see how much energy remains. If the battery energy is low, plans to replace the pulse generator should be made

Replacing the AICD system

Just like any other type of battery, the battery in an AICD system wears down over time. Then the AICD pulse generator needs to be replaced. How long your AICD pulse generator lasts depends on what settings your doctor programs into the device and how much therapy you receive. Your doctor will unplug the old pulse generator from the leads. The leads are checked to make sure they are still working properly. Then they are connected to the new AICD pulse generator. Finally, a test is performed to make sure the new system is working properly.

Your friends' and family's responses to the AICD system

The AICD system can be a source of security for you and your friends and family. Thinking about it this way can help them become more comfortable with your device when you are away from emergency care. Some friends

and family members may want to learn about cardiopulmonary resuscitation (CPR). They can contact the local Red Cross for more information.

Understanding your emotions

It's natural for patients and their families to feel anxious about the device at first. Feelings such as denial, sadness and anger are perfectly normal. You have experienced something very stressful: a life-threatening event that changed your thoughts and feelings about your health. While having the AICD system is positive because it can treat your arrhythmias, some people feel vulnerable because they depend on an implanted device. The good news is those feelings generally don't last more than a few months.

Sources of support

Talking with other AICD patients is often helpful while adjusting to your AICD device. They can provide valuable information on how they adjusted to the AICD device. Ask your doctor or nurse if there is a local AICD support group of patients.

Notes

Use this page to write down questions you want to ask your doctor or notes if you receive therapy from your AICD. Things that may be helpful for your doctor include:

- The date and time you received therapy.
- What you were doing just before and after therapy was delivered.
- What physical sensations you had just before and after therapy delivery.

AICD system and personal information

Have your heart doctor or nurse complete the information on these pages before you go home from the hospital.

AICD Device Model #: _____ Serial #: _____
Lead Model #: _____ Serial #: _____
Date Implanted: _____

If you notice anything unusual with your device, call your doctor or electrophysiology (EP) nurse.

Electrophysiologist Name: _____
Electrophysiologist Phone Number: _____
Electrophysiology Nurse Name: _____
Electrophysiology Nurse Phone Number: _____
Cardiologist Name: _____
Cardiologist Phone Number: _____

Glossary

adaptive rate: The ability of a pulse generator to adjust its rate up or down in response to bodily needs, activity or exercise

arrhythmia: any rhythm of the heart that is faster or slower than the average heart rate and regularly for most people.

atria: the upper chambers of the heart, specifically the right atrium and left atrium. The atria collect blood as it comes into the heart and fill the lower chambers (ventricles) with blood.

bradycardia: a slow heartbeat, typically less than 60 beats per minute (bpm). It may be caused by the sinoatrial (SA) node not working properly or by a condition called heart block.

cardiac arrest: the heart beats very fast or stops completely so that no blood is being pumped out to the body.

cardioversion: the stopping of a fast heart rate by an electrical impulse that is delivered at the same time as the heartbeat. It uses low to moderate energy to restore the heart's normal rhythm.

defibrillation: the stopping of a fast heart rate by delivering a high-energy electrical shock to restore the heart's normal rhythm.

defibrillator: an internal or external device that can deliver an electric shock to stop extremely rapid and irregular heartbeats and return the heart to a normal rhythm.

ECG/EKG (electrocardiogram): a test to show your heart rhythm printed out on paper. The test shows how electrical impulses travel through your heart. Your doctor can tell what kind of rhythm

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you have by looking at the printed pattern of your heartbeat.

electromagnetic field: invisible lines of force that are the result of the use of electricity, such as anything plugged into an outlet or operated by a battery.

electromagnetic interference (EMI): produced by an electromagnetic field. If it is strong enough, it may interfere with the operation of an AICD system; this happens only on very rare occasions.

electrophysiology (EP): test or study: a test where wires are inserted into your heart to identify and measure the type of electrical signals in your heart. The test results can help your doctor recognize your abnormal heart rhythm, determine how well medications work, and decide what treatment is best. The test also can be used to see how well you AICD system operates during your abnormal heart rhythm.

heart attack: also called myocardial infarction (MI), this occurs when an artery that feeds the heart becomes blocked. As a result, blood does not get to some parts of the heart and some of the heart tissue dies. The symptoms may include nausea, shortness of breath and/or pain in the chest, arm or neck.

heart rhythm: another word for a heartbeat. You may hear your doctor refer to your rhythm as being normal or irregular, meaning there is an abnormality. A normal heart rate typically ranges from 60 to 100 beats per minute at rest.

lead: an insulated wire that carries the heart signal to the pulse generator and energy from the pulse generator to the heart. The leads are attached to the surface of the heart or passed into your heart through the veins.

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pectoral: the area near the breast or upper chest.

programmer: microcomputer-based equipment used to communicate with the pulse generator. It provides information during testing and follow-up exams. The doctor uses the programmer to adjust the pulse generator so that it senses and treats your arrhythmias. The programmer can, for example, help your doctor discover when the pulse generator needs to be replaced.

pulse generator: the part of the AICD system that contains the electronics and the battery; it is implanted under the skin in the abdominal or pectoral area.

sinoatrial (SA) node: the small area in the upper right chamber of your heart that normally generates an electrical impulse. This impulse runs through the heart and causes the heart to beat.

ventricle: one of the two lower chambers of the heart. The right ventricle sends blood to the lungs, and the left ventricle passes blood carrying oxygen to the rest of the body.

ventricular fibrillation (VF): a very fast, irregular heart rate caused by abnormal impulses starting from several areas of the ventricle. The heart beats so fast that it is unable to pump any blood to the body. A heart in fibrillation may beat over 300 times a minute. A person in fibrillation passes out and needs immediate medical attention in order to live.

ventricular tachycardia (VT): a fast heartbeat caused by abnormal impulses coming from a single area of the ventricle. The rapid rate of 120-250 beats per minute may produce dizziness, weakness, blind spots and, eventually, unconsciousness.

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