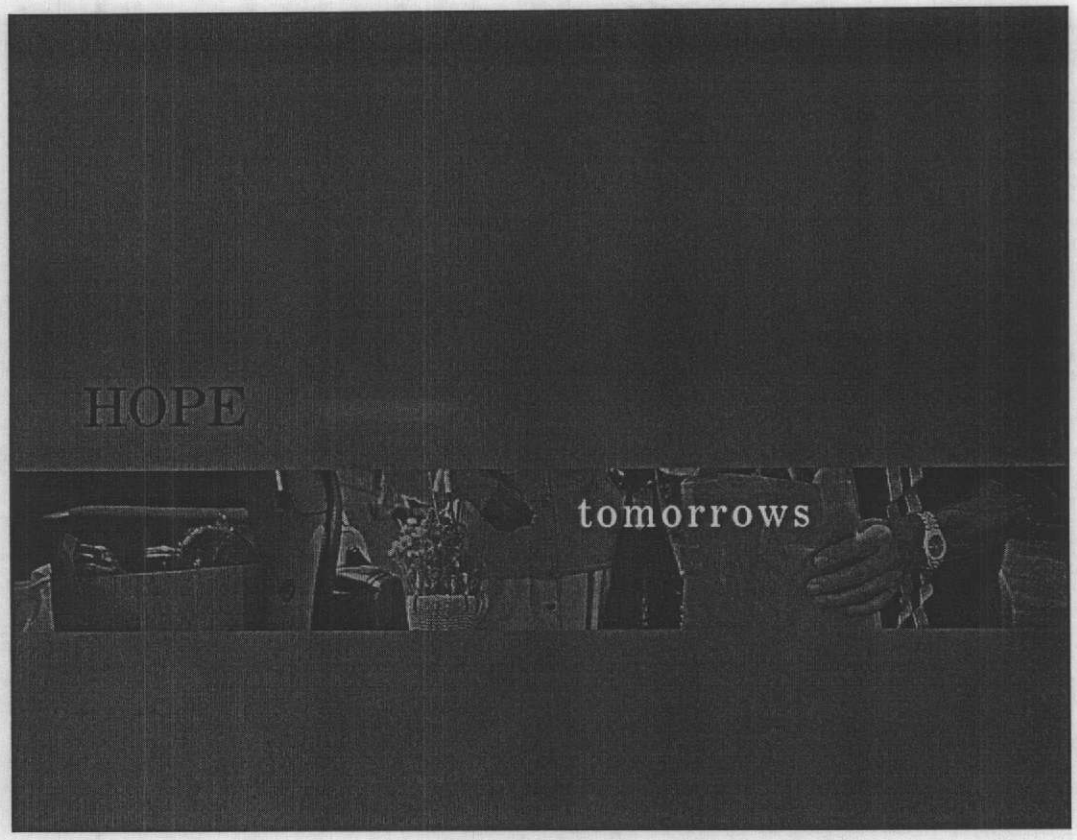
A Handbook for Patients

GUIDANT

Cardiac Resynchronization Therapy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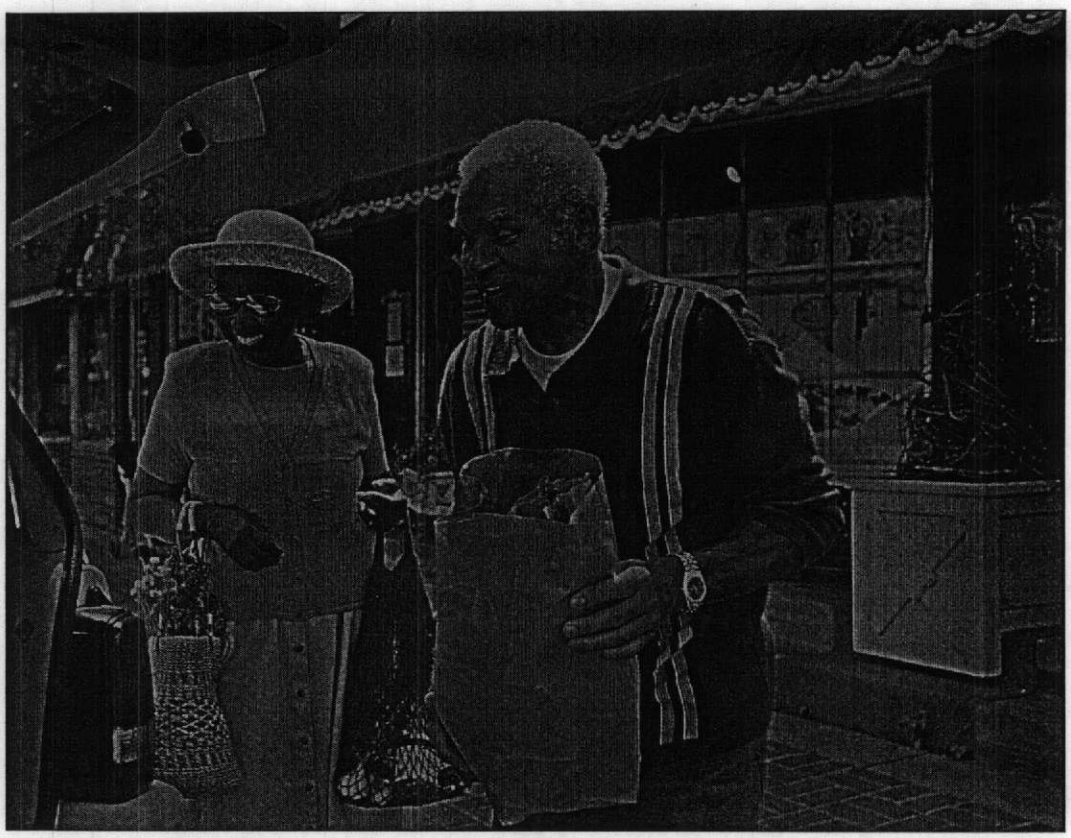

Introduction

Your doctor has determined that you have a form of heart failure and has recommended a Guidant heart failure system to treat your condition.Your doctor may also call this heart failure system a cardiac resynchronization therapy pacemaker (CRT-P). A CRT-P is designed to help your heart pump more effectively and meet your body's need for blood flow.

This handbook will tell you how a Guidant CRT-P system treats heart failure. It discusses activities that you can begin and those you should avoid after your surgery. It talks about

some of the changes that may occur in your life. It will also answer many questions patients typically have.

The glossary is located at the front of the handbook. It provides explanations to many of the words you will see in the upcoming pages, as well as those you may hear from your doctors or nurses.

Glossary

Adaptive rate
The ability of a device to adjust its rate up or down in response to bodily needs, activity, or exercise.

Asynchrony
A condition in which the heart fails to maintain a normal timing sequence between atrial and ventricular contractions.

Atrio-Ventricular (AV) node
A cluster of cells located in the wall between the right and left atrium, just above the ventricles. This part of the heart's electrical pathway helps carry signals from the atria to the ventricles.

Atrio-Ventricular (AV) synchrony
The normal timing sequence for an atrial contraction followed, after a fraction of a second, by a ventricular contraction

Atrium (plural: atria)
One of the two upper chambers of the heart, specifically the right atrium and left atrium. The atria collect blood as it comes into the heart and pump blood into the lower chambers (ventricles).

Bradycardia
A slow heartbeat, typically less than 60 beats per minute (bpm).

Cardiac arrest
The heart beats very fast or stops completely so that blood is not being pumped out to the body.

Cardiac resynchronization therapy pacemaker (CRT-P)
The device monitors your heart's signals and coordinates the ventricles to help them contract at the same time, allowing the heart to pump more effectively.

Device
See pulse generator.

ECG/EKG (electrocardiogram)
A graphic representation of your heart's electrical signals printed on paper. The graph shows how electrical impulses travel through your

heart. Your doctor can tell what kind of rhythm you have by looking at the printed pattern of your heartbeat.

Electromagnetic field

Invisible lines of force that are the result of electrical fields (produced by voltage) and magnetic fields (produced by current flow). Electromagnetic fields decrease in strength the farther they are from their source.

Electromagnetic interference (EMI)

An electromagnetic field that interferes with the operation of a device; this happens only on rare occasions.

Heart attack

Also called a myocardial infarction (MI). A heart attack, or damage to the heart muscle, occurs when an artery that feeds the heart becomes blocked. As a result, blood does not reach some parts of the heart and some of the heart tissue dies. Symptoms of a heart attack may include pain in the chest, arm, or neck, nausea, and/or shortness of breath.

Heart block

A condition in which the electrical signals of your heart's natural pacemaker (SA node) are delayed or do not reach the ventricles.

Heart failure

A medical condition in which the heart muscle is unable to pump enough blood to meet the body's needs.

Heart rhythm

A series of heartbeats. You may hear your doctor refer to your rhythm as being normal or irregular. A normal heart rate typically ranges from 60 to 100 beats per minute (bpm) at rest.

Lead

An insulated wire that is connected to the device and implanted in the heart. The lead delivers pacing pulses from the device to the heart. The leads are passed into your heart through a vein.

Myocardial infarction (MI)

Also called a heart attack. This occurs when an artery that feeds the heart becomes blocked. As a result, blood does not reach some parts of the heart and some of the heart tissue dies. The symptoms

may include pain in the chest, arm, or neck, nausea, and/or shortness of breath.

Pacemaker system
Consists of a pulse generator (also called a device) and leads. A pacemaker system is implanted to monitor your heart rhythm and treat dangerously slow rhythms.

Pectoral
The area near the breast or upper chest. This is a common area for a device implant.

Programmer
Microcomputer-based equipment that is used to communicate with the device. It provides information during testing and follow-up exams. The doctor or technician uses the programmer to adjust the device so that it treats your heart failure.

Pulse generator
Also called a device. This is the part of the heart failure system that contains the electronics and the battery; it is implanted under the skin in the pectoral or abdominal area.

Sino-Atrial (SA) node

The heart's natural pacemaker. The SA node is a small group of specialized cells in the upper right chamber of the 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 pumps blood to the lungs, and the left ventricle pumps blood carrying oxygen to the rest of the body.

Your heart's natural pacemaker

Your heart works as both a pump and an electrical organ. It is able to beat because it produces electrical impulses. These impulses travel through the electrical pathways of your heart, causing the muscle contraction that pumps blood throughout your body.

Normally these impulses come from a small area in your heart called the sino-atrial (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 heart (the atria) they contract at the same time. The atrial contraction completes

filling the two lower chambers (the ventricles) with blood. As the electrical impulse travels to the ventricles, it causes them to contract (Figure 1). The contraction of the heart muscle (ventricles) is what you feel as a heartbeat. After a brief rest, the cycle begins again.

Heart failure

The heart may begin to fail for a variety of reasons. One reason may be a result of muscular damage from a heart attack. The heart can also be weakened from prolonged periods of pumping against high blood pressure in the arteries.

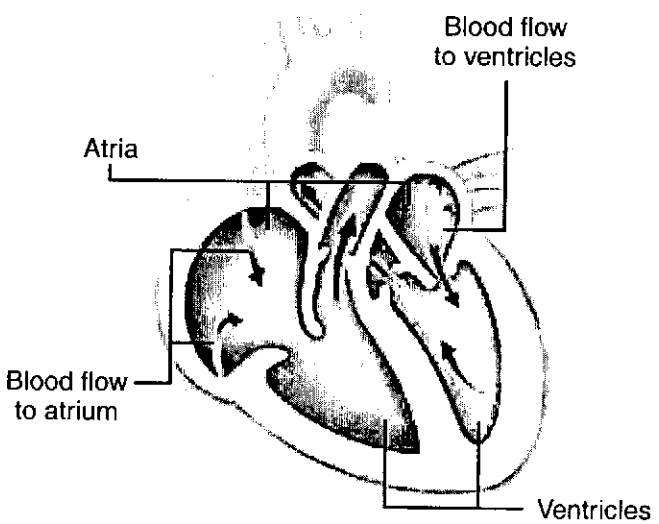

Figure 1. The heart and its blood flow.

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Over time, the heart muscle weakens and becomes enlarged (Figure 2). The ventricles are unable to contract with the same strength or coordination as before. As a result, the heart chambers may not completely empty with each beat. Because of this, the flow of blood and oxygen to the body is poor.

This failure of the heart to pump efficiently and meet the body's need for blood and oxygen is called heart failure. When you have heart failure, you may feel short of breath, tired or faint. Medications are often used to treat heart failure and its symptoms. However, some people may also need a CRT-P to help the heart beat more efficiently again.

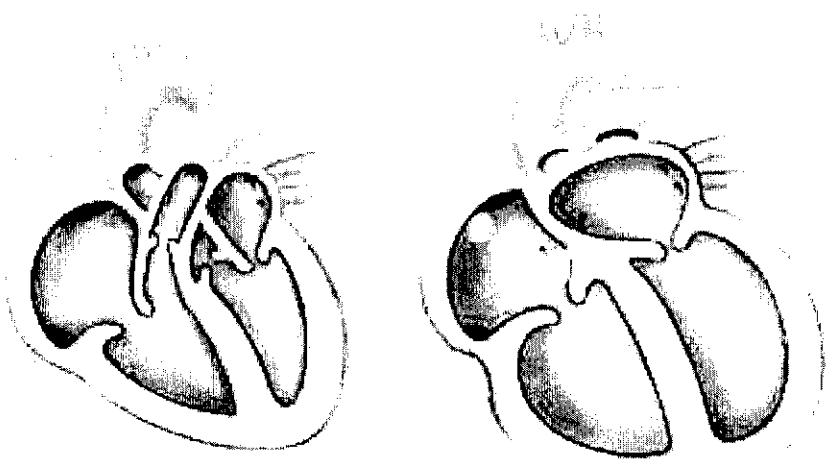

Figure 2. An example of an enlarged heart.

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Bradycardia

Sometimes heart failure patients also have slow heart rates. 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 atria and the ventricles. The natural pacemaker signals sent out by the SA node could be delayed or may not reach the ventricles.

During bradycardia, the chambers of the heart do not contract often enough to supply the proper amount of blood to your body. If you have bradycardia (Figure 3), you might frequently feel tired or possibly faint.

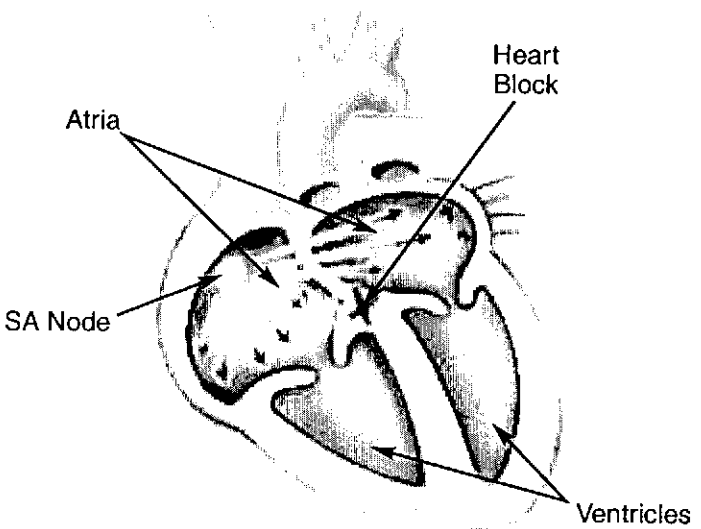

Figure 3. An example of heart block.

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Your Guidant CRT-P System

A CRT-P system provides pacing therapy to coordinate the contractions of your ventricles. It is also able to treat and monitor a slow heart rhythm. The system consists of a pulse generator, which is typically implanted in your chest. Three leads, which are implanted inyour heart, are connected to the pulse generator.

The pulse generator

The pulse generator is a small computer. It runs on a battery that is safely sealed within the device's case. The device continuously monitors your heart's function and delivers

electrical energy to coordinate the contractions. It can also pace your heart when it senses a slow rhythm.

As the device treats and monitors your heart, it can also store information about your heart. Your doctor can review this information using a small computer called a programmer to better evaluate your heart rhythms. Your doctor can also determine if the programmed treatment is appropriate. If necessary, he or she can change the device's settings with the programmer.

The leads

A lead is an insulated wire connected to the pulse generator and implanted in your heart. The lead carries the heart signal

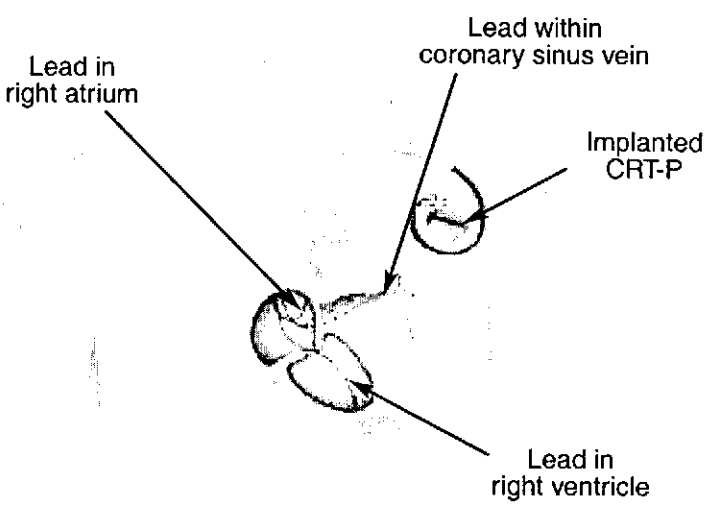

Figure 4. An implanted CRT-P system.

to the pulse generator. It then carries energy from the pulse generator back to the heart to coordinate your heart's contractions and rhythm.

Implanting your CRT-P system

A heart failure system is implanted during a surgical procedure. Because the surgery is done using anesthesia, it is generally painless. During the procedure, your doctor will insert two leads into a vein, usually through a small incision near your collarbone. The doctor then passes the leads through the vein into your heart, where the tips of the leads rest directly against your heart's inner wall. A third lead is placed within a

coronary vein. This is a vein that lies on the outside surface of your heart. This vein is on the heart's left side (Figure 4).

In some cases, a patient may need to have the third lead placed through an incision on the side of the chest instead of through a vein. This procedure is called a thoracotomy. Your doctor will discuss if this type of chest surgery is an alternative for you.

After the leads are positioned, the device and leads are tested to make sure they clearly record your heart signal and cause your heart to contract. After this testing, the device is placed in position, usually below the collarbone, just beneath the skin.

Implant risks

As with any surgical procedure, it is important to understand that there are risks associated with the implantation of a CRT-P system. Some risks encountered during the implant procedure include infection, tissue damage, kidney failure, and an irregular heart rhythm. Also, the lead could poke a hole in the heart or in the vein on the outside of the heart.

Some of the risks encountered after the device is implanted may include, but are not limited to, the following: the lead(s) may move out of place in the heart. The electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart

tissue and nerves. The device might not appropriately treat your heart rhythms appropriately coordinate the contractions of your left and right ventricles. It could also be unable to appropriately detect and treat a slow heart rhythm.

It is important that you talk with your doctor about the risks and benefits associated with the implantation of this system.

After your implant

As you recover from your implant surgery, you may find that your CRT-P system will allow you to return to a more active lifestyle. It is important that you become actively involved in your recovery by following your doctor's instructions, including:

- Report any redness, swelling, or drainage from your incisions.
- Avoid lifting heavy objects until instructed by your doctor.
- Walk, exercise, and bathe according to your doctor's instructions.

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- Don't wear tight clothing that could irritate the skin over your device.
- Contact your doctor if you develop a fever that does not go away in two or three days.
- Ask your doctor any questions you may have about your CRT-P system, heart failure, heart rhythm, or medication.
- Avoid rubbing your device or the surrounding chest area.
- If directed by your doctor, limit arm movements that could affect your lead system.
- Avoid rough contact that could result in blows to your implant site.

- Tell your other doctors, dentists, and emergency personnel that you have a CRT-P.

Contact your doctor if you notice anything unusual or unexpected, such as new symptoms, or symptoms like the ones you experienced before you received your device.

Medications

Your CRT-P system is designed to help treat your heart condition. However, you may need to continue taking certain medications as well. It is important that you follow your doctor's instructions regarding any medications.

Activities and exercise

Your doctor will help you decide what level of activity is best for you. He or she can help answer your questions about lifestyle changes, travel, exercise, work, hobbies, and resuming sexual intimacy.

Your identification card

Whether you are going away for the weekend or running a quick errand, carry your Guidant Medical Device Identification card with you. The card will alert medical and security personnel that you have an implanted heart failure system.

You will be given a temporary Guidant Medical Device Identification card when you receive your device. Guidant will mail you a permanent Medical Device Identification card about 6-8 weeks after your implant.

Your Medical Device Identification card contains your name, your doctor's name and phone number, and the model numbers of your device and leads.

If you move or select a new doctor, please call Guidant Medical Records at 1-800-728-3282 to update your records. When you notify us of a change, we will send you a new identification card reflecting these changes.

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Living with your CRT-P

Your CRT-P will automatically coordinate the contractions of your left and right ventricles. It will also monitor and treat a slow heart rhythm. It is important to follow your doctor's instructions and keep your scheduled follow-up appointments. You should also do the following:

- Ask your doctor any questions you may have about your CRT-P, or if you notice anything unusual with your device.
- Take the medications prescribed for you as instructed by your doctor.

- Carry your identification cards and medications list with you at all times.
- Tell your family doctor, dentist, and emergency personnel that you have a CRT-P.

Special considerations

Your doctor might ask you to avoid activities where the risk of unconsciousness could endanger you or others. These activities might include driving, swimming or boating alone, or climbing a ladder.

Driving

Driving laws and symptoms caused by your heart condition 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.

When to call your doctor

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

- Have a heart rate that drops below the minimum rate set for your device.
- 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 device, heart failure, heart rhythm, or medications.
- Plan to travel or move.
- Notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you had before you received the device.

Follow-up visits

Your doctor will schedule regular follow-up visits. It is important that you attend these visits, even if you are feeling well. Your device has many programmable features; follow-up visits can help your doctor program your device to best meet your individual needs.

To check your device, the doctor or nurse will use a programmer. The programmer communicates with the device from outside your body through a wand that is placed over your skin.

A typical follow-up visit takes about 20 minutes. During your follow-up visit, the doctor or nurse will use the programmer to interrogate, or check, the device. They will review the device's memory to evaluate its performance since your last visit. If necessary, they will adjust the device's programmed settings. They will also check the battery to see how much energy is left.

What you should know about your device's battery

A battery, safely sealed inside the device, provides the energy needed to coordinate your heart's contractions and

monitor and pace your heart rhythm. Just like any other type of battery, the battery in a heart failure system is used up over time.When that happens, the device needs to be replaced. How long your device lasts depends upon the settings your doctor programs into the device. It is also affected by how much pacing therapy you receive.

How will you know if your device's battery is running down?

CRT-P batteries have a very predictable behavior over time. Your device will regularly check its own battery. At every follow-up visit, the doctor or nurse checks to see how much energy is remaining in the battery. When the battery's energy level decreases to a certain point, the device will need to be replaced.

Replacing the device

When your CRT-P is replaced, your doctor will surgically open the pocket of skin where the device is located. He or she will disconnect the old device from the leads. The leads are checked to make sure they will work properly with the new device. The doctor will then connect the leads to the new device. Finally, a test is performed to make sure the new system is working properly.

After the testing is over, the pocket of skin is stitched closed. The entire procedure takes about an hour. It is considered a minor operation, and you should be able to return to normal activities soon.

Important facts about your device

Operating household appliances and tools

Your device has built-in features that protect it from interference produced by most electrical appliances. Most of the things you handle or work around on a daily basis are not going to influence your device. However, your device is sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. The following lists provide guidelines for safe interaction with many common tools, appliances, and activities.

Precautions and warnings

If you use any of the following items, it is important that you keep them the recommended distance away from your device to avoid interaction:

Items that are safe under normal use:

- Blenders
- CD/DVD Players
- Electric blankets
- Electric can openers
- Electric invisible fences
- Electric razors
- Fax/copy machines

- Hair dryers
- Heating pads
- Hot tubs/jacuzzis

NOTE: *Consult with your doctor before using a hot tub or jacuzzi. Your medical condition may not permit this activity; however, it will not harm your CRT-P.*

- Laser tag games
- Microwave ovens
- Pagers
- Personal computers
- Remote controls (TV, garage door, stereo, camera/video equipment)
- Stoves (electric or gas)
- TV or radio towers (safe outside of restricted areas)

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- Tanning beds
- Vacuum cleaners

Items that can be used, but should remain at least 6 inches (15 cm) away from your device:

- Cellular phones

NOTE: *For more information on cellular phones, refer to the section "Cellular phones" on page 42.*

Items that can be used, but should remain at least 12 inches (30 cm) away from your device:

- Battery-powered cordless power tools
- Bingo wands (magnetic)
- Police radio antennas
- Chain saws

- Corded drills
- Lawn mowers
- Leaf blowers
- Shop tools (drills, table saws, etc.)
- Slot machines

NOTE: *Contact with some metallic slot machines may interfere with your device. If you have questions, call Guidant Technical Services (1-800-227-3422).*

- Snow blowers
- Stereo speakers

Items that should remain at least 24 inches (60 cm) away from your device:

- Arc welders
- CB radio antennas

Items that should be avoided at all distances:

- Body fat measuring scales (handheld)
- Jack hammers
- Running motors and alternators

NOTE: *Avoid leaning over the alternator of a running automobile. Alternators create large magnetic fields that could affect your device.*

- Stun guns

If you have questions about the EMI safety of a particular appliance, tool or activity, please call Guidant Technical Services at 1-800-227-3422.

Anti-theft devices

Don't linger near anti-theft devices in doorways of department stores and public libraries. They are sources of

EMI and can affect your device. It is important that you walk through anti-theft devices at a normal pace.

Airport security

Your device contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your device. Tell security personnel that you have an implanted device and show them your Medical Device Identification card.

Airport security wands could temporarily affect your device. If possible, ask to be hand-searched instead of using a handheld wand. If a wand must be used, inform the security personnel that you have an implanted device. Tell the

security personnel that the search must be done quickly and not to hold the wand over your device.

If you have questions about airport security, call your doctor or Guidant Technical Services at 1-800-227-3422.

Cellular phones

Keep your cellular phone at least 6 inches (15 cm) away from your device. Your cellular phone is a source of EMI and could affect your device's operation. This interaction is temporary, and moving the phone away from the device will return it to proper function. To reduce the chance of interaction, follow these precautions:

- Maintain a distance of at least 6 inches (15 cm) between the cellular phone and your device. If the phone transmits more than 3 watts, increase the distance to 12 inches (30 cm).
- Hold the cellular phone to your ear on the opposite side of your body from your device.
- Don't carry a cellular phone in a breast pocket or on a belt if that places the phone within 6 inches (15 cm) of your device.

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 device.

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Dental and medical procedures

Tell your dentist and doctors that you have a heart failure device. Some of the equipment used in medical procedures might affect your device. Some medical procedures you should avoid include:

Magnetic resonance imaging (MRI): This is a diagnostic test that uses a strong electromagnetic field. MRI scans can severely damage your device and should not be performed. Hospitals keep MRI equipment in rooms marked with signs that indicate magnets are inside. Do not go inside these rooms.

Diathermy: This uses an electrical field to apply heat to tissues in the body and could damage your device. If diathermy must be used, talk with your doctor about any special precautions to protect your device.

Electrocautery: This is used during surgical procedures to stop vessels from bleeding. If electrocautery must be used, talk with your doctor about any special precautions to protect your device.

Therapeutic radiation treatment for cancer: This procedure can affect your device and will require special precautions. If you should need radiation treatment, talk with your doctor about any special precautions to protect your device.

Transcutaneous Electrical Nerve Stimulation (TENS) unit: This is a device prescribed by physicians or chiropractors for control of chronic pain. A TENS unit can affect your device and will require special precautions. If you must use a TENS unit, talk with your doctor about any special precautions to protect your device.

Most medical and dental procedures will not affect your device. Some examples include:

- Dental drills and cleaning equipment
- Diagnostic x-rays
- Ultrasound procedures
- EKG machines
- CT scans

If you need to undergo any surgical procedures, tell your dentist and/or doctor that you have a heart failure system. They can contact your cardiologist to find the best way to provide treatment.

If you have questions about a specific appliance, tool, medical procedure or piece of equipment, please talk with your doctor or call Guidant Technical Services at 1-800-227-3422.

Summary

It's natural for you to feel anxious or nervous about receiving a CRT-P system. Talking with other CRT-P patients is often helpful while adjusting to your new device. Ask your doctor, nurse, or Guidant representative if there is a local patient support group in your area.

The information presented in this handbook is intended to help you understand more about your heart condition and your device. If you have questions about what you have read, be sure to ask your doctor or nurse. They are your best resource for information on your particular needs or situation.

When is this device used?

Your doctor has recommended a pacemaker with heart failure therapy because you have heart failure symptoms despite drug therapy. Also, your ventricles might not contract at the same time to meet your body's need for blood flow. Refer any questions you may have about when this device is used to your doctor.

When is this device not used?

There are reasons why a patient should not receive a pacemaker with heart failure therapy. Overall, patients who have additional medical conditions that may not allow the CRT-P to function appropriately should not receive a device.

Refer any questions you may have about when this device is used to your doctor.

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Your Guidant contact information

By Mail:
Guidant Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112

By Telephone:
24 Hours: 1.800.CARDIAC (1.800.227.3422)
Worldwide: +1.651.582.4000

On the Internet:
www.guidant.com

Guidant Medical Records:
1.800.PATDATA (1.800.728.3282)
7 a.m. - 7 p.m. (Central Time), Monday-Friday
email: medical.records@guidant.com

Visit www. guidant. com to view additional patient information and to sign up to receive LifeBeat, Guidant's patient newsletter.

Your CRT-P system information

Have your doctor or nurse complete the information on this page before you go home from the hospital.

CRT-P Model Number: _____

CRT-P Serial Number: _____

Implant Date: _____

Programmer System Model Number(s): _____

Lead Model/Serial Number: _____

Lead Model/Serial Number: _____

Lead Model/Serial Number: _____

Your medical contact information

Electrophysiologist Name/Phone Number:

_____

Cardiologist Name/Phone Number:

_____

Medications (list):

_____

_____

Hospital Name/Address/Phone Number:

_____

_____

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Questions for your doctor

Use this space for questions you want to ask your doctor.

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Life

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CRT-P

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