

Helping people with cardiac devices live full, active lives.



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More Is Not Always Better Metabolic Syndrome Increases Your Risk



Roger is a big man, in more ways than one. He carries his weight around his waist. His blood pressure, cholesterol and blood glucose levels are all above normal.

Roger went to the clinic for his annual physical exam. He went home knowing he had metabolic syndrome.

Metabolic syndrome is the name for a group of risk factors that occur together. They increase your chances of developing heart disease, diabetes, and stroke.¹

About 47 million people in the United States have metabolic syndrome.¹ That is almost 15 percent of the all the people living in America.

In general, people with metabolic syndrome are twice as likely to develop heart disease as people without metabolic syndrome. They are five times as likely to develop diabetes.¹

1. National Heart Lung and Blood Association Diseases and Conditions Index, www.nhlbi.nih.gov/health/dci/index.html. Accessed June 9, 2009.

2. Parish J, Adam T, Facchiano L. Relationship of Metabolic Syndrome and Obstructive Sleep Apnea. *J Clin Sleep Med*. 2007 August 15; 3(5): 467-472.

3. National Heart Lung and Blood Association, *Aim for a Healthy Weight*. http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm. Accessed June 9, 2009.

Metabolic syndrome is the name for a group of risk factors that occur together.

Risk Factors

Here's a brief look at what you need to know about metabolic syndrome.

The five conditions below are all risk factors for heart disease. If you have one of these risk factors you are likely to have others. The more of these risk factors you have, the higher the risks to your health.^{1,2}

- **A higher than normal fasting blood glucose level:** This is measured at 100 mg/dL or higher. You are still at risk if you are on medicine to treat high blood glucose levels.
- **A lower than normal HDL cholesterol level:** This is less than 50 mg/dL for women or less than 40 mg/dL in men. You are still at risk if you are on medicine to treat low HDL.
- **A higher than normal triglyceride level:** This is 150 mg/dL or higher. You are still at risk if you are on medicine to treat high triglycerides. Triglycerides are a type of fat found in the blood.
- **A large waistline:** This is a waist size of 35 inches or more for women and 40 inches or more for men.
- **A higher than normal blood pressure measurement:** This is a blood pressure measured at 130/85 mm Hg or higher. You are still at risk if you are already on medicine to treat high blood pressure.

Your health care provider may mention metabolic syndrome when a person has at least three of these risk factors.¹

Heart-Healthy Lifestyle Basics

Making healthy lifestyle choices is a good way to help you reduce your risk for heart disease, stroke, diabetes and other diseases. Here are a few things to consider when thinking about heart-healthy basics:

- Know your blood glucose, cholesterol and blood pressure levels. A cholesterol blood test will show your levels of LDL (low-density) and HDL (high-density) cholesterol and triglycerides.
- Keep a healthy weight. If you are overweight, losing just 10 percent of your body weight can help you reduce your risk factors for heart disease.³
- Eat a healthy diet and try not to overeat. Eat fewer calories and less saturated fat. Eat plenty of whole grains, fish, and fruits and vegetables. Choose unsaturated fats when eating fats. Limit the amount of salt you eat. Limit the amount of alcohol you drink.
- Increase your physical activity. Talk to your health care provider about what kind of physical activity is best for you. If you're medically able, get at least 30 minutes of moderate activity, such as brisk walking, at least 5 days a week.
- Take all of your medications as prescribed.

Go Online to Find Details about Your Device

Do you want to know more about your implanted device? Now you can go to LifeBeat Online to learn more.

Boston Scientific offers easy to read spec sheets about your device.

Each spec sheet has a picture of the device, an overview of how it works, and battery information.

- From www.lifebeatonline.com, select Resources for Patients.
- Then select Pacemakers, Defibrillators, or Heart Failure Devices.
- Find the name of your device.
- Then select the name to open the spec sheet.

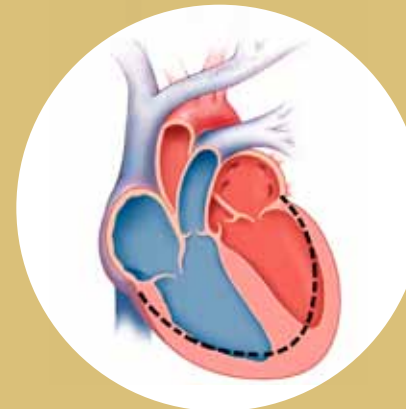
If you have more questions, please contact Patient Services at 1-866-484-3268.



Learning Center

Understanding Your Heart Failure Classifications

If you have heart failure, you may wonder what your health care provider means when he or she describes your heart failure as Class I, II, III, or IV. In this article, we will look at why heart failure classes are important and what the terms mean.



Enlarged heart

Your Heart and Your Symptoms

Heart failure does not mean that your heart has stopped working. It means that your heart isn't as strong as it should be. Some people with heart failure do not have symptoms. But many do. Common symptoms of heart failure include feeling tired, shortness of breath, swollen ankles and weight gain. It can eventually lead to death.

If you have heart failure, it is important to tell your health care provider what you feel and how badly you feel. This helps decide the treatment that will be best for you.

New York Heart Association (NYHA) Classification

The NYHA classification provides a simple way for your health care provider to label your heart failure symptoms. Your health care provider will place your heart failure into one of four categories. If you feel pretty good most of the time, you may be Class I. If you feel badly most of the time, you may be Class IV.

Class I (the mildest form):

You can perform everyday activities and not feel out of breath or tired.

Class II:

Everyday activities make you feel slightly tired and out of breath.

Class III:

Even minor activity causes you to feel tired and out of breath.

Class IV (the most severe):

You're tired and short of breath even at rest.

Your NYHA classification may change as your symptoms change.

In most cases, heart failure cannot be cured. However, many treatment options available today are effective. Your NYHA classification will help you and your health care provider talk about which treatment options may be right for you.

What is the “Stages of Heart Failure” system?

Your health care provider may use another classification system to show how your heart failure is progressing. This is called the “Stages of Heart Failure” system.¹

The American Heart Association and American College of Cardiology developed this system. It uses a scale with letters from A to D to represent four stages. This system is not based on how you feel. Your heart failure stage is based on your risk of developing heart failure. It includes how well your heart is functioning now, if there is any damage to your heart, and your symptoms.

Stage A:

You do not have heart failure now, but are at high risk.

Stage B:

You do not have heart failure symptoms yet, but your heart has been damaged by disease or other factors.

Stage C:

Your heart has been damaged in some way and you have had heart failure symptoms.

Stage D:

You have severe heart failure symptoms and require specialized therapies.

If you do not already have heart failure, this system stresses that you can delay or even prevent it. The key is to know your risk factors and take steps to get them under control.

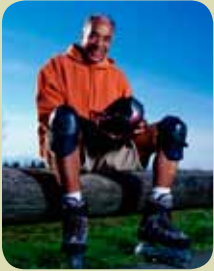
¹Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult—summary article. J Am Coll Cardiol. 2005;46:1116–1143.



Richard N. Fogoros, M.D. (Dr Rich) is a former professor of medicine, and a longtime practitioner, researcher and author in the fields of cardiology and cardiac electrophysiology. Dr. Fogoros is also on the LifeBeat editorial board.

ICD Patient Stories

LifeBeat attempts to bring real-life patient experiences into living with a heart rhythm device. In this issue we present common stories from ICD patients. Some patients received ICD therapy. Some patients learned about their heart disease. Other patients learned how the Latitude system works. You may find your experience in one or more of these stories.



I like to exercise but...

George was running on his treadmill when he felt a shock from his device. He stopped the treadmill and sat down. He felt fine. So why did the ICD give him a shock?

Dr. Fogoros:

When you exercise your heart rate goes faster. If your heart goes fast enough when you exercise, your ICD device may deliver therapy based on its settings. Your ICD device is programmed by your health care provider based on your heart condition.

George has an ICD because he is at risk of dying from sudden death. We need to remember that the device should treat a dangerous rhythm if it occurs. The ICD device uses heart rate and other features to control when the device delivers therapy. We can look at how fast George's heart rate was during exercise. Then the rate that the ICD device uses can be then changed to not treat the exercise heart rate, but still treat the dangerous rhythm when it occurs.

We asked Dr. Richard Fogoros to share what he tells patients in these situations.



After my shock, I found out I had atrial fibrillation.

Lois sat in her favorite chair whenever she felt her heart beat in an odd way. It would feel like it was skipping beats. Today she also felt a hard punch in her chest. Why did that happen?

Dr. Fogoros:

The ICD system saves a picture of the heart rhythm it treats. That picture showed that Lois's heart rhythm was atrial fibrillation. Atrial fibrillation is often discovered when a patient has an implanted device. Patients may receive ICD therapy for fast rates caused by atrial fibrillation. The ICD device can be programmed to know that a heart rhythm does not need to be treated.

The picture of the rhythm can help the health care provider determine the best treatment for Lois. Treatments for patients with atrial fibrillation include medicine to prevent blood clots and medicine to slow down the heart rate. Cardioversion may be used to deliver electrical therapy to the patient's chest to restore a normal heart rhythm. Some patients may need an ablation procedure. Ablation procedures try to stop the fast atrial rate from making the ventricles beat fast in the future.

Individual patients should consult with their physician about their specific medical condition.

The Latitude system checks
her ICD device at home.



The clinic called me about the battery in my ICD.

Karen goes to the clinic to have her ICD device checked twice a year. Other times, the Latitude system checks her ICD device at home. She was surprised when the clinic called to schedule her ICD device to be replaced. How did they know that?

Your implanted ICD device is designed to work
properly around most appliances and equipment.



I still work on my cars, but not when the engine is running.

Every time Harry worked on the running engine of his car, he felt dizzy. He found out that the engine caused the pacemaker in his ICD device to think he had a heart rate, when in fact he doesn't!

Dr. Fogoros:

Remote monitoring systems, like the Latitude patient management system, can help the health care team take better care of patients. These systems can check the device at home and tell the clinic if the patient's device needs any attention. The battery in Karen's device is measured every day. When the Latitude system checked that information at the end of the week, it showed that the ICD device was ready to be replaced. The Latitude system then sent that information to the clinic.

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Dr. Fogoros:

Your implanted ICD device is designed to work properly around most appliances and equipment. Most things you handle or work near every day will not cause a problem. However, some machines can create electromagnetic interference (EMI). Harry's running car created a large EMI field. That is why we do not recommend working under the hood while the engine is running.

EMI occurs when the signals from an electromagnetic field temporarily interfere with how the implanted device works. That was what Harry felt. The pacemaker in the ICD device may see the EMI as a heart rate and not pace the heart. The ICD device may see the EMI as a fast heart rate and deliver shock therapy. For all device patients, the closer your implanted device is to the EMI source, the stronger the effect. The farther away, the less likely you will experience an EMI effect. EMI effects do not usually harm your device.

WHAT IS A CLINICAL STUDY? Part 1

A clinical study, or trial, is a scientific study that can involve people. You may hear that a new study was published. You may hear that a product was shown to help patients based on clinical research.

In this article, we will look at clinical studies and what they mean to patients. In future issues, we will look at how clinical research can lead to more options for patients with heart disease. We will also talk to patients that have been part of a clinical study.

Why are there clinical studies?

A clinical study tries to answer a question about a certain disease or health issue. Each study tries to find better ways to prevent, diagnosis, or provide treatment. Many treatments used today are the result of past clinical research.

At one time, most heart patients were treated with only medicine. Today, clinical studies have made ICDs a big part of treating patients with certain heart problems. For example, the MADIT II clinical study asked if patients who have had a heart attack live longer with heart medications alone or with heart medications and an implanted cardioverter defibrillator (ICD). The study showed that some heart patients could be helped even more when an ICD is part of their therapy.

What happens in a clinical trial?

Patients in a clinical study work with a research team at a local clinic or hospital. The team members may include doctors, nurses, and other health care providers. They will provide the patient (participant) medical care, monitor the patient's health carefully, and give specific instructions about what the patient should/should not do in the study.

In the United States, the federal government and a hospital's ethical review board watch clinical studies to make sure that patients are treated as safely as possible.



As the clinical study moves forward, information about the study is presented at scientific meetings and in medical journals. Information is also sent to government agencies, such as the Food and Drug Administration (FDA).

Who can join a clinical study?

The approved study document, or protocol, lists the types of patients that qualify to be in the study. The following requirements are common when a clinical study looks at implanted cardiac device therapy. The patient must:

- have a certain heart condition, such as coronary artery disease.
- have symptoms from a disease like heart failure
- be on certain medications.

Your health care provider may invite you to join a clinical study. This is an important personal

decision. It is often helpful to talk to a health care provider, family members, or friends about joining a study.

Controlled clinical studies is one way to find new, safe, and effective treatments for disease. Patients in a study take an active part in their own care. Many patients benefit from access to new treatments for their disease. Patients also receive expert care from the medical experts and health care facilities during the study.

For more information on clinical studies, go to www.clinicaltrials.gov.



C.A.R.E. FOUNDATION

Since 1995, the Cardiac Arrhythmias Research and Education (CARE) Foundation has actively raised money to support research and education programs in inherited electrical and structural heart conditions. Electrical heart conditions include Long QT Syndrome (LQTS) and Brugada's Syndrome. Structural heart conditions include hypertrophic cardiomyopathy (HCM) and arrhythmogenic right ventricular cardiomyopathy (ARVD/C).

Advocacy

- CARE worked for passage of the Genetic Information Nondiscrimination Act (GINA), which makes it illegal to deny employment or insurance to a person based on their genetic risk or inherited disorder.

Research

- CARE has granted nearly \$500,000 to young investigators to study cardiac arrhythmias and sudden death.

Education

- Each year, CARE's Heart to Heart educational programs bring together patients and affected families to network, ask questions, and learn about the latest clinical breakthroughs from physician experts.

Patient and Family Support

- Each year, CARE responds to requests for support from over 3,000 patients and families and more than 1,000 health care professionals.

**For more information go to www.longQT.org
427 Fulton Street, Seymour, WI, 54165 800.404.9500**

ICD Systems from Boston Scientific CRM

ICD Indications and Usage

ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

Contraindications

Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. Such damage can result in patient injury or death. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

Precautions

For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events from implantation of the ICD system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system - patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only.
(Rev. M)

LATITUDE® Patient Management System from Boston Scientific CRM

The LATITUDE Patient Management system is used to remotely communicate with a compatible pulse generator device from Boston Scientific CRM and send data to a central database. The LATITUDE system is contraindicated for use with any pulse generator other than a device from Boston Scientific CRM.

The LATITUDE system is designed to tell your doctor within 24 hours if alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. However, alert notification cannot occur if:

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- Your device and the Communicator cannot establish and complete a communication session. This session must be initiated by you if you have a device that uses inductive telemetry (Communicator that has a wand).
- The Communicator becomes damaged or it malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.

Up to two weeks may go by before the LATITUDE system detects the events mentioned above, and additional time may be required for clinic notification and resolution of the condition.

Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by reviewing supporting diagnostic information stored in the implanted device and viewing information on the LATITUDE clinician website.

The wand and wireless Communicator uses a radio frequency (RF) communication system to communicate with an optional weight scale and blood pressure monitor. This communication can be disrupted by electromagnetic interference. Avoid placing your Communicator next to or in the immediate vicinity of other wireless products and sources of electromagnetic energy. The wireless Communicator uses RF to also send and receive signals from the implanted device (RF enabled devices only). Using the blue Interrogate button more than as prompted by your Communicator or as instructed by your physician may lead to a decrease in the battery life of your implanted device. Your communicator is designed to be used in the continental US, Alaska, Hawaii, and Puerto Rico. These devices are available by prescription only.

(Rev.K)



Cardiac Rhythm Management

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