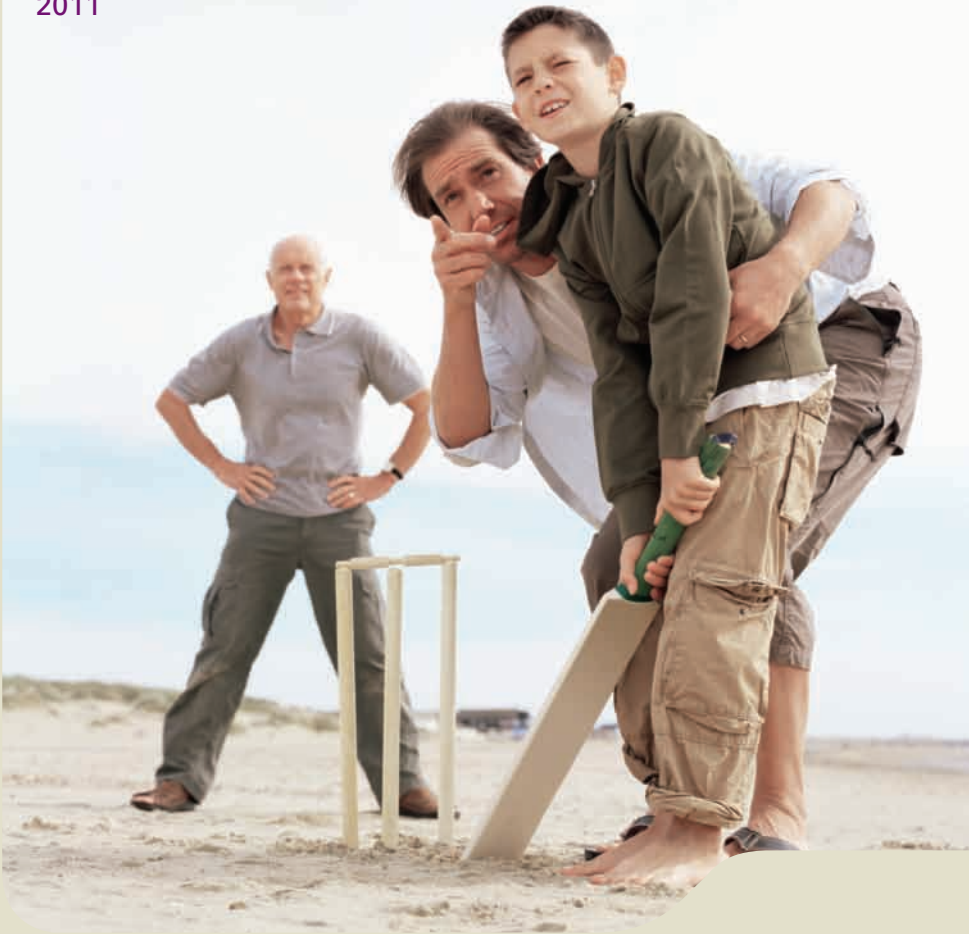


Lifebeat

2011



CRV

Cardiology, Rhythm
and Vascular

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LATITUDE[®]

Remote Patient Management and You

Have you arrived at your doctor's office and seen reports about your implanted device? How did they get there? It all starts at home with the Boston Scientific LATITUDE Communicator.

Let's look at how information gets from your house to your healthcare provider.

What to do with the “Thing in the Box”: the LATITUDE Communicator

Your doctor prescribed your LATITUDE Communicator as part of the Boston Scientific ICD (implantable cardioverter defibrillator) or CRT-D (cardiac resynchronization therapy defibrillator) device implanted in your chest.

*If you need help you can call Patient Services for assistance –
1.866.484.3268.*



1

Your Communicator is mailed to your home – use the helpful resources inside the box to learn about the Communicator.



2

Set up your Communicator as soon as you receive it – it plugs into your phone line and electrical outlet.



3

After set up, your doctor can begin monitoring your defibrillator.

It is recommended that your LATITUDE communicator stay near your bedside or some other place where you spend long periods of time.

What the LATITUDE Communicator does:

- Whether the Communicator sits next to your bed or on a chair-side table, it should be level with your implanted device. It looks side to side and operates at night.
- The Communicator looks for your device at a scheduled time. If you are not near it when it starts looking for your device, it will continue to look for you every 10 minutes.
- When the Communicator finds your device, it sends information about your device to a secure website using your phone line. Examples of information sent include battery and lead data, heart rates, arrhythmias, and therapy events.



What the LATITUDE Communicator doesn't do:

- The Communicator does not change how your device is programmed to treat your heart.
- The Communicator does not cost you any money. However:
 - o When your healthcare provider uses information from the Communicator, it may result in a copayment from you for checking the information on the website.
 - o The information sent in is similar to what your healthcare provider sees when you go to the clinic.
- The Communicator does not give you a shock if you touch it.
- The Communicator does not take pictures of you.

Meet Robert



Robert H.* is a 56-year-old man who was implanted with a TELIGEN® ICD device in September 2010. Everything was fine with Robert until about a month ago when he started feeling dizzy and had shortness of breath several times a week. He expected it to pass, but then his device clinic called him to set up a follow-up visit for a new problem he had developed.

When looking at information obtained from his LATITUDE system, the clinic found the cause of Robert's symptoms—atrial fibrillation. New treatments were prescribed and Robert's symptoms went away. He feels better knowing that the clinic has a solid connection with his LATITUDE Communicator and his device.

Follow the Data

Your healthcare team will check your device based on your personal health needs and clinical follow-up schedule. With the LATITUDE Patient Management System:

- Your doctor can monitor your heart and device between follow-up visits.
- You may not need to visit your healthcare provider's office as often.

Your Communicator also works with a wireless weight scale and blood pressure cuff. Information from those devices can help your healthcare provider monitor your heart failure status.



Note: Individual symptoms, situations, circumstances, and results may vary. Please consult your physician or qualified healthcare provider regarding your condition, appropriate medical treatment. The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice.

*The patient's real name and photo have not been used in this newsletter.

Meet Margaret



Margaret D.* is a 76-year-old heart failure patient. She was implanted with a COGNIS® CRT-D biventricular defibrillator device in March 2009. She uses the LATITUDE blood pressure cuff and weight scale every day as prescribed by her doctor, even when she doesn't feel very good.

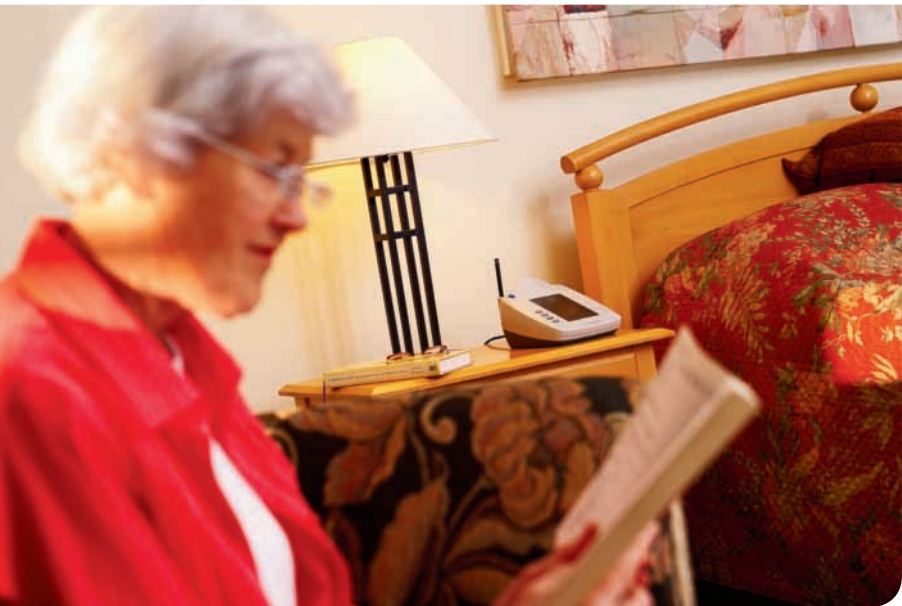
The clinic called Margaret to schedule a follow-up visit. She did not expect to be seen for another month. When she arrived, her healthcare team was not surprised that she was a little sluggish and breathless. The LATITUDE system told them that she had put on weight, which could be an early sign of trouble with her heart failure. After a brief hospital stay to gain control of her fluid status and adjust her medications, Margaret went home feeling better and comfortable that her COGNIS CRT-D, LATITUDE Communicator, her doctor and his staff were always working together to watch her heart and health.

Note: Individual symptoms, situations, circumstances, and results may vary. Please consult your physician or qualified healthcare provider regarding your condition, appropriate medical treatment. The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice.

You are not Alone –

As of May 2011, there are more than 195,000 patients are enrolled in the LATITUDE system in the United States.

The LATITUDE Patient Management System is designed to provide you and your family members with peace of mind and assurance that your heart health and specific cardiac device information can be monitored between clinic follow-ups from the convenience of your home.



Direct From Patient

In 2010, Boston Scientific engaged a research group to better understand patients like you. Two types of focus groups were formed in Minneapolis, Philadelphia, and San Francisco. One type of focus group included patients with heart failure who did not have device implants. The other type of focus group included patients with heart failure who had an ICD device or CRT-D device. More than 50 patients were asked about these topics:

- Features of devices, including size, shape, and longevity
- Attitudes surrounding cardiac condition and diagnosis
- Attitudes toward devices
- Experience with devices (for those with implants)
- Concerns and challenges before and after implant

Here's what we found in the survey:¹

- In addition to the focus groups, we surveyed nearly 150 more patients about the topics. Here is what 85% of patients would prefer a device that is thinner and wider, rather than thick and narrow.
- 73% of patients are concerned about battery life and device longevity.
- 66% of patients are worried their device will fail to shock when necessary, or deliver inappropriate shocks.



In the study, patients discussed samples of plastic cardiac devices marked by letters.

Perspectives from patients



“If you wear a silk blouse, it’s going to show... that’s one of my concerns and that’s why I would pick that [device], it’s thinner.”

– Renee, congestive heart failure



“I want it to last as long as possible, worry-free.”

–Gary, congestive heart failure



“The [device] went off five times...so I was thinking this was going to happen to me all the time.”

–Donna, CRT-D patient

Do you feel the same way as these patients?

It is important to remember that you are not alone. Many patients have heart failure and wonder about receiving implanted cardiac device therapy.

Approximately 625,000 people are implanted with a Boston Scientific ICD device and more than 300,000 people are implanted with a Boston Scientific CRT-D device.²

LifeBeat is one way we try to answer your questions and provide helpful information about living with an implanted cardiac device.

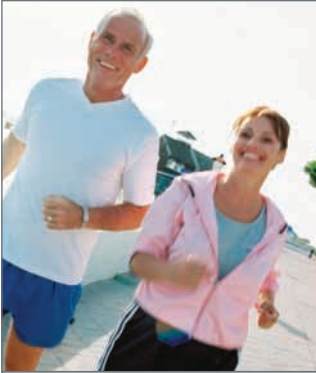
Let us know what you think.

Contact us at www.lifebeatonline.com

1. Q-essential High Voltage Patient Survey, January 2011. Double-blind online survey administered by 3rd party vendor; conducted among 189 high voltage device patients.

2. Boston Scientific Patient Population Model as of March 2011.

Have fun in the summertime



The American Heart Association says, “Take the first step. Start with walking!”

This summer, nearly 1 million walkers will participate in more than 450 events, raising funds to save lives from this country’s No. 1 and No. 3 killers – heart disease and stroke.¹

The great thing about walking is that you can do it anywhere. You can tailor your route and speed to fit your needs. Brisk walking for about 30 minutes a few times a week has been shown to significantly decrease the risk of heart attack and coronary artery disease.¹ It also gives you more energy, helps you relax, tones your muscles, burns calories, and help control your appetite. So get out and go!

And walking isn’t your only option. Physical activity takes many forms – gardening, yoga, mild weight training, swimming, biking – the warm weather offers many opportunities to increase your physical activity every day. Of course, remember to talk to your healthcare provider before you start any new exercise routine.

1. Excerpts from: “Why Start Walking?” www.startwalkingnow.org/. Accessed June 13, 2011.

The American Heart Association says,

“Take the first step. Start with walking!”



Low-impact Exercise

Low-impact exercise can burn a high number of calories and build strength without putting joints and muscles at undue risk. Whether you are recovering from surgery, maintaining your fitness level, or trying to start a new exercise routine, low-impact exercise could be the best choice for you.



Swimming

When the days get hotter, get in the water. Swimming is a total-body workout. While it is joint friendly, it can be a challenging activity. So this summer, before you jump in, talk to your healthcare provider. Don't forget to wear sunscreen.



Golfing

When the weather is mild, head for the golf course. Walking and stretching before teeing off can boost heart strength and minimize strained muscles. Also, golf is a fun activity to enjoy with friends. Socializing on the course can relieve stress and keep the sport interesting. Make sure to wear loose, comfortable clothing. And don't forget – stay hydrated and wear sunscreen.

In addition to exercise, we have more access to a variety of fresh seasonal foods. It is the perfect time to improve your eating habits. This means eating less fat, less sodium, fewer calories, and more fiber.

What do you do to be heart-healthy?

Let us know by sending an email to LifeBeatOnline@bsci.com or sending a note to LifeBeat Editor (5-393), Boston Scientific CRV, 4100 Hamline Ave North, St. Paul, MN 55106

Your Medical ID Card

For the Places You Want To Go

You received a permanent identification (ID) card from Boston Scientific shortly after receiving your pacemaker or defibrillator device. Do you know where it is now?

Medical Device ID			Boston Scientific	
Implanted Cardiac Rhythm Patient				
Patient: Dave Johnson				
Physician: JOE D ANDERSON MD				
Patient Telephone: (555) 555-5555				
MFG	Product	Model/Serial	Implant D	
Guidant	AICD	1851 00909	09-OCT-20	
Guidant	Lead	0125 909910	09-OCT-20	
Guidant	Lead	497-01 887766	09-OCT-20	
Guidant	Lead	82-0002-8601 00599SK	09-OCT-2006	
Guidant	Accessory	6831 123456	09-OCT-20	
Oscor	Lead	PY48SBV	09-OCT-20	

Implanted Cardiac Rhythm Management Patient	
Contact physician for medical questions or emergency	
For Security Personnel	For Patients
MAGNETIC SECURITY WANDS MAY AFFECT DEVICE FUNCTION. DO NOT HOLD WAND OVER DEVICE.	1.866.484.3268 (USA) – 1.651.582.4000
	Outside USA: 001.651.582.4000
	For Medical Personnel
	1.800.227.3422 – 651.582.4000
	www.bostonscientific.com
	www.lifebeatonline.com
<small>If your name, mailing address, or physician changes, please call Medical Records: 1.866.484.3268, 7 AM – 7 PM Central Time, Monday – Friday CRM8-1371-0710</small>	

You should always have your Medical Device ID card with you. The Medical Device ID card identifies you as a person with an implanted cardiac device.

Many patients think the Medical Device ID Card is only used when they go through security at the airport, but there are security systems in many places you visit every day. The Medical ID card can help answer questions should the security system react to your implanted device.

You may need to show your ID card...



If you go to the courthouse
to renew your license...



If you go to the ER or hospital
for surgery or treatment...



If you go through a
scanner at the library
to check out a book...



If you go to the dentist
for an oral procedure...



If you go to the
airport to travel...

In addition, you may see more than one healthcare provider. You may be prescribed a medical treatment from a doctor who doesn't follow your implanted device. Be sure to tell your device-following physician about any treatment to ensure that your device records are up to date.

If you do not have your permanent Medical Device ID card, call Boston Scientific at 1-866-484-3268 to order a card.

LATITUDE® Patient Management System from Boston Scientific CRM

Important Safety Information

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 new pulse generator 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.
- Our device and the Communicator cannot 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 is damaged or 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. 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 your medical care. Alerts can be verified by viewing information on the LATITUDE clinician website and reviewing supporting diagnostic information stored in the implanted device.

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. M)

Important Safety Information

Cardiac Resynchronization Therapy Devices from Boston Scientific CRM

Cardiac resynchronization therapy pacemakers (CRT-P) and defibrillators (CRT-D) are designed to treat heart failure patients who may or may not have symptoms (CRT-D), or who may have symptoms despite the best available drug therapy (CRT-P and CRT-D). They are also designed to help your heart pump more effectively and meet your body's need for blood flow. CRT-P and CRT-D systems are not for everyone, including people with separate implantable cardioverter-defibrillators (CRT-P only) or certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who should not receive this device include: patients who have additional medical conditions that may not allow the pacemaker to function appropriately (CRT-P only) and patients whose ventricular rhythm disturbances or heart failure have a reversible or temporary cause. In some cases, the device may be unable to detect or appropriately respond to your heart rhythm (CRT-P and CRT-D) or may deliver inappropriate shocks (CRT-D only). In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. These devices are available by prescription only. Individual results may vary. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1.866.484.3268.

(Rev. G)

Implantable Cardioverter Defibrillators from Boston Scientific CRM

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. But it is not for everyone, including people with certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who should not receive this device include: patients whose ventricular rhythm disturbances have a reversible or temporary cause and patients with certain types of atrial rhythm disturbances. Procedure risks include infection and tissue damage. In some cases, the device may not respond to irregular heartbeats or may deliver inappropriate shocks. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This device is available by prescription only. Individual results may vary. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1.866.484.3268.

(Rev. G)

Pacemakers from Boston Scientific CRM

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. But it is not for everyone, including patients with certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who have additional medical conditions that may not allow the pacemaker to function appropriately should not receive a device. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This device is available by prescription only. Individual results may vary. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1.866.484.3268.

(Rev. G)



Cardiology, Rhythm and Vascular

One Boston Scientific Place
Natick, MA 01760-1537 USA
www.bostonscientific.com
www.lifebeatonline.com

Medical Professionals:

1.800.CARDIAC (227.3422)

Patients and Families:

1.866.484.3268

Correction:

In the Fall 2010 issue of LifeBeat, a footnote that explained the differences in the number of patients listed in the three charts was left off the page. The information in the charts came from 194,039 patients, but not all of them provided details about gender, age, and device indication.