

## My follow-up questions:

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# A GUIDE TO THE PATIENT NOTIFIER FEATURE

CAUTION : FEDERAL LAW (USA) RESTRICTS CARDIAC ARRHYTHMIA MANAGEMENT DEVICES TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

Brief Summary: Please review the appropriate literature accompanying the device for a complete listing of warnings and precautions.

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## Frequently Asked Questions

### The St. Jude Medical patient notifier feature.

A patient notifier is a feature available in some pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices. It is designed to alert you to significant changes in the performance of your device and to let your doctor know that your system may need attention. Issues with implanted devices are rare. This feature is not intended to concern you. On the contrary, it is available to provide an added level of support for you and for those who care for you.

### How does my patient notifier work?

As you go about your normal activities, your device is providing you with important therapy. Your doctor has programmed settings in your device specifically to meet your unique needs. In addition, he or she can program the device to sense significant changes in your device's performance. When the device senses one of these changes, it will signal you that attention is needed. This helps to ensure that your device continually provides you with the therapy you require.

### Why is a patient notifier important?

A patient notifier is able to alert you right away to system performance changes that your doctor deems important. Previously, in devices without patient notifiers, changes were only discovered at routinely scheduled follow-up visits with your doctor. As such, it could be months before the doctor saw an important change and, during that time, mild to severe symptoms could have developed.

### How does the device signal me that my device needs attention?

St. Jude Medical uses two types of patient notifiers in its products. One works by sending a short series of vibrations that are felt throughout the chest area, while the other works by sending a two-tone audible signal. The vibratory patient notifier is used in some ICDs and CRT defibrillators (CRT-Ds), while the audible patient notifier is used in some pacemakers and CRT pacemakers (CRT-Ps).



## What does a vibratory alert feel like? Does it hurt?

The vibration emitted from the device is much like a cell phone vibration. It is noticeable but subtle.

## Does the vibration feel like a shock?

No, the vibratory notifier pulses gently; a shock is generally more remarkable.

## What does the audible alert sound like?

The audible alert is a six-second, two-tone signal.

## How will the notifier alert me to changes in my condition or device?

As a standard, the alert will sound or vibrate for six seconds, followed by 16 seconds of quiet, after which there will be another six seconds of sound or vibration, followed by a 10-hour wait period before the cycle repeats. The signal pattern can be programmed differently by your doctor, who may also choose to test the notifier in the office, so that you can become familiar with its sound or vibration.

## If my device sends me an alert, does that mean it has stopped working?

No, the alert means that your device may need attention. It could mean that the battery is reaching end of service (an alert is sent well in advance of the battery losing power), or it can be programmed so that your doctor can detect changes in your heart's rhythm. It does not necessarily mean that therapy is compromised.



## What should I do if my device sends an alert?

It is important that you discuss with your doctor what he or she would like you to do if your device sends an alert. Your doctor is familiar with you and is the best person to determine your course of action.

## Will a vibratory alert set off a shock in my ICD or CRT-D?

The patient notifier feature is separate from the feature that detects a life-threatening arrhythmia in an ICD or CRT-D. An alert will not set off a shock, nor will it affect therapy in any cardiac rhythm management devices.

## Will microwaves, airport security systems or other electronic devices set off my patient alert?

No, the patient notifier feature is unaffected by environmental factors.

## Because I have a patient notifier, does it mean that I only have to get my device checked when it alerts me? Can I forego follow-up appointments?

No, you should get your device checked on a regular basis as determined by your doctor. Consider that having a device is like almost any other form of therapy, such as taking medication. With medication, even if you are feeling well, it is appropriate to see your doctor periodically to make sure that the medications are continuing to accomplish their desired results. If they are no longer working as intended, it may be necessary to change the dose or prescribe additional medication. Additionally, with medication, it is important to perform blood tests to make sure that the medicine is not causing a problem undetectable through any other means.

The same is true for your device. It is important to assess it periodically, to make sure it is working correctly, and, at times, to adjust the settings to achieve the desired results. Likewise, your doctor needs to make sure that no problems are developing that are otherwise undetectable, but that may impact the effectiveness of pacing therapy.

The patient notification features help to assess the mechanical function of the pacemaker and, to some degree, the device's interaction with your heart. It is an extra feature that lets you and your doctor know whether your device needs attention between your regularly scheduled appointments.

