

LATITUDE Patient Management allows anytime, anywhere access to patient status and device data

Patient background:

- 63-year-old male
- Ischemic cardiomyopathy
- Atrial and ventricular arrhythmias with ablation
- Heart failure (HF)
- Third implanted device; currently has a CONTAK RENEWAL® 3 RF CRT-D

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Allied Health Professional: Laurie Sinn, R.N., B.S.N., clinical nurse coordinator

History: The patient has a history of HF and ischemic cardiomyopathy complicated by arrhythmias. His first device was implanted as a result of syncope and a positive electrophysiology test. Per clinic protocol, this patient was on a six-month follow-up schedule, but due to a recent industry recall, he now requires an interrogation every three months. This patient and his spouse spend most of their time traveling the countryside in their recreational vehicle (RV) and do not have a permanent residence or home telephone.

Incorporating LATITUDE Patient Management into this patient's care: LATITUDE has allowed the patient to continue his normal life and to travel freely in his RV with his portable LATITUDE Communicator. The increased follow-up demand was a limiting factor for this patient until the launch of the new LATITUDE Patient Management system.

Situation: Sinn established a remote follow-up protocol.

Action: Regardless of where they are, every three months the patient and his spouse spend one night in a hotel of their choice where he plugs his Communicator into the phone line and proactively sends a wireless transmission to the clinic using the patient-initiated interrogation feature.

Response: The patient no longer has to limit his distance from the clinic and can stay connected to his primary clinicians while maintaining the "latitude" his lifestyle requires.

Heart Rhythm Society Draft Recommendations Report

"The Heart Rhythm Society (HRS) recommends that CRM device manufacturers develop and utilize wireless and remote monitoring technologies to:

- Identify abnormal device behavior as early as possible
- Reduce under reporting of device malfunctions by determining the functional status of an implanted device more frequently and more accurately."²

²www.hrsonline.org

Individual results may vary.

Individual symptoms, situations, and circumstances may vary. Patients should consult a physician or qualified health provider regarding their medical condition and 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. This information is to be used in conjunction with other resource material, which may include the applicable patient handbook, Boston Scientific device physician's manual and any implant accessories instructions for use.

Guidant CRT-D Systems

Indications and Usage

Guidant Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction (EF \leq 35%) and QRS duration \geq 120 ms.

Contraindications

There are no contraindications for this device.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to, or death of, the patient. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2 pads) immediately available during conversion testing. 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 CPR are present during post-implant device testing should the patient require external rescue. 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 activated implanted pulse generator to diathermy since diathermy may damage the pulse generator. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial only modes in patients with heart failure because such modes do not provide CRT. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use the CRT-D with a separate pacemaker system. This combination could result in CRT-D/pacemaker interaction. The emulator is not intended for use as a permanent lead electrode and must be removed from the patient. It is for one-time use only. Do not resterilize.

Precautions

For information on precautions, read the following sections of the product labeling: sterilization, storage and handling; implantation and device programming; follow-up testing; pulse generator explant and disposal; environmental and medical therapy hazards; home and occupational environments. Advise patients to avoid lingering near anti-theft devices (electronic article surveillance [EAS]). Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events from implantation of the Guidant CRT-D system include, but are not limited to, the following: allergic/physical reaction, death, erosion/migration, fibrillation or other arrhythmias, fracture/insulation break (lead or accessory), hematoma/seroma, inappropriate therapy, infection, lead tip deformation and/or breakage, procedure related, psychologic intolerance to an ICD system—patients susceptible to frequent shocks despite antiarrhythmic medical management, random 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.

LATITUDE® Patient Management System

Intended Use

The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible Guidant pulse generator device and transfer data to a central database.

Contraindications

The LATITUDE Patient Management system is contraindicated for use with any pulse generator other than a compatible Guidant device. For contraindications for use related to the Guidant pulse generator, refer to the System Guide for the Guidant pulse generator being interrogated.

Precautions

The LATITUDE system is designed to notify clinicians within 24 hours if pulse generator alert conditions are detected. 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.
- The pulse generator and the Communicator cannot establish and complete a telemetry session.

Up to two weeks may elapse before clinic notification to address events mentioned above.

Adverse Effects

None known.

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Cardiac Rhythm Management

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