

LATITUDE® Patient Management System

Clinical Case Study Abstract



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SYNOPSIS

In this case, the data from the LATITUDE® Patient Management system alerted Dr. Lipman to a weight gain in a patient with heart failure. That same day, Dr. Lipman was able to bring the patient in and adjust her diuretics before symptoms developed. In addition, the patient experienced arrhythmia events that were brought to Dr. Lipman's attention through the LATITUDE system.

ABSTRACT

The case involves a 40-year-old female with a history of nonischemic cardiomyopathy. She had a single kidney, so renal issues complicated heart failure management. The patient was classified as being in New York Heart Association functional class IV despite optimal pharmacologic therapy, and despite the fact that she closely monitored food and fluid intake. She had a history of frequent — often weekly — hospitalizations due to her heart failure. She underwent implantation of a CONTAK RENEWAL® 3RF CRT-D device and was enrolled on the LATITUDE Patient Management system.

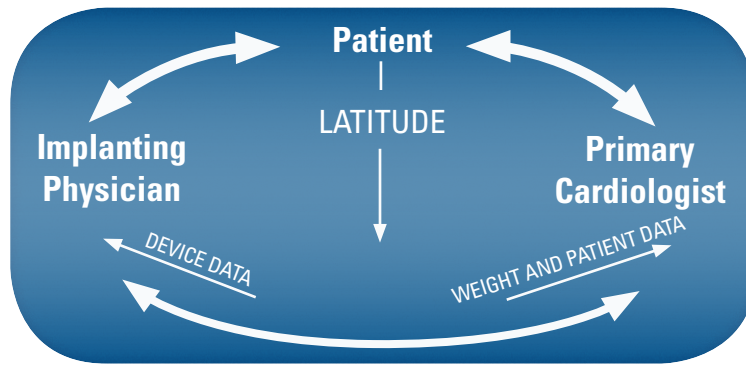
Data from the LATITUDE Patient Management system about the patient's weight gain allowed Dr. Lipman to quickly initiate action. That same day, the patient was contacted by phone and then brought in for an office visit.

LATITUDE® Patient Management		05 Sep 2007
Facsimile Alert		
To: WBI101, WBI101 Clinic: WBI101 CLINIC 2 Fax Number:		
From: Boston Scientific LATITUDE Patient Management Phone Number: 800.227.3422 <i>If this transaction is not received in good order, please call 800.227.3422.</i>		
Patient		
Address:	INDIC 001	Date of Birth:
INDIC 001		
Patient Phone Number:		
Service:		
Last In-Office Visit Text:		
Last Remotely Monitored:	24 Oct 2006	
Patient Alert Information		
⚠ 3000EGC00 - Weight gain of at least 5 lb. in a week or at least 2 lb. average over a two or more day period.		
<small>This facsimile message is intended only for the individual to whom it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If you have received this facsimile in error, please notify us immediately by telephone and return the original message to us at the address below via the US Postal Service.</small>		
Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112-5798		Tel 1.800.CARDIAC (800.227.3422)

Alert Notification: Clinicians received a faxed Yellow Alert for "Weight gain of at least 5 lb. in a week or at least 2 lb. average over a two or more day period."



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Action Taken: Depending on the physician preference, specific device and patient heart health alerts can be independently selected by both the primary cardiologist and the implanting physician. In this case, Dr. Lipman quickly addressed the situation by seeing the patient the same day she was notified of the weight gain.

The LATITUDE Patient Management system provided early detection and notification of this patient's weight gain. By responding quickly to the faxed notification, Dr. Lipman was able to see the patient the same day and adjust her diuretics. For Dr. Lipman, preventing hospitalization was a priority in this case, since this patient had previously been hospitalized so often for heart failure complicated by renal limitations.

In addition, the system alerted Dr. Lipman to the patient's atrial and ventricular arrhythmia episodes, which contributed to progression of her heart failure. As a result of the arrhythmias, Dr. Lipman prescribed anti-arrhythmic medications as well.

Gary Dunbaugh, ARNP, stated, "[The LATITUDE system] can give me convenient access to the patient [device and heart health] information because I can receive fax alerts based on the parameters that patient is set on."

Dr. Lipman stated, "Prior to LATITUDE we had [the patient] weigh herself daily on her regular scale. But often we wouldn't receive communications until she was up 10 lbs or actually in distress I think the LATITUDE system is clearly more sophisticated than other [systems] on the market. It can give you more information than just what's going on in the defibrillator. We've been able to certainly look at arrhythmogenic problems that we suspect. However, the additional information with weight and blood pressures has helped us manage the actual clinical symptoms of CHF, where a lot of the other devices that have remote access are simply concerned with the device itself and not with the other ramifications in a patient who might have congestive heart failure."

Contact your Boston Scientific Sales Representative to view the full case study presentation, which includes audio clips from Randee Ellen Lipman, MD, FACP, FACC, as well as a more detailed description of this case.

LATITUDE® Patient Management System from Boston Scientific CRM

Intended Use

The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database.

Contraindications

The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the pulse generator, refer to the System Guide for the pulse generator being interrogated.

Precautions

The LATITUDE system is designed to notify clinicians within 24 hours if new pulse generator alert conditions are detected by the Communicator. Pulse generator data will typically be available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that data will not be available and 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. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
- The Communicator becomes damaged or it malfunctions.

Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above and additional time may be required for notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission will be available.

Adverse Effects

None known.

Refer to the product labeling for specific instructions for use. Rx only.

(Rev. H)

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