

SUMMARY

The LATITUDE[®] Patient Management system remotely connects patients and health care practitioners, enabling transfer of actionable device and patient related data at scheduled intervals.

For patients enrolled in LATITUDE, remote monitoring can be performed daily or weekly, during scheduled remote follow-ups, and during patient-initiated interrogations.

Following device interrogation in the patient's home (via the communicator), a patient's device data and relevant patient health information are transferred to the secure LATITUDE website for clinician viewing.

The LATITUDE system can be configured to send alerts to the patient's physician(s) if a condition is detected which warrants notification.

Appendix A provides a list of LATITUDE Alerts by CRT-D and ICD family.

Products Referenced

LATITUDE[®] Patient Management System, COGNIS[®], TELIGEN[®], PUNCTUA[™], ENERGEN[™], INCEPTA[™]

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation and indications for use, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
ICD: Implantable Cardioverter Defibrillator

Contact Information

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LATITUDE[®] Alerts (Clinical Event Notifications)

LATITUDE[®] alerts are designed to provide device following physicians (typically electrophysiologists) and patient health following physicians (typically cardiologists or heart failure specialists) with advance notification (between in-office visits) of a potential heart-health or device problem regarding a patient enrolled in the LATITUDE Patient Management system. Alerts, which are categorized as red or yellow, are sent to physicians if they are detected during a LATITUDE device check scheduled or initiated between office visits.

Red Alerts

Red alerts are declared when conditions are detected that could potentially leave the patient without device therapy. The LATITUDE system is designed to notify clinicians if a red alert is detected by the communicator. Red alerts cannot be deselected (i.e., configured Off) in the LATITUDE system, however, several notification preferences can be customized. To customize notification preferences, physicians should contact their local sales representative or International LATITUDE Customer Support and complete a Red Alert Notification Form.

NOTE: During remote device interrogations, red alert conditions within the device may be reported through the LATITUDE website. The physician will not be contacted for red alerts that have previously been reviewed, including:

- Alerts dated prior to the most recent programmer interrogation.
- Alerts for which notification has previously been provided.
- Alerts that have been reviewed and/or dismissed from the LATITUDE System.

Yellow Alerts

If selected, yellow alerts are declared when a certain device condition or patient heart-health issue is detected that may warrant physician review or investigation. Physicians may configure notification preferences as follows:

- Individually select which yellow alerts they receive. They may choose to receive all, some, or no yellow alerts.
- Select delivery preferences for yellow alerts. They are available via the LATITUDE website and optionally via fax machine.

Daily Measurement Alerts

Intrinsic amplitude and lead impedance are measured daily by the implanted device. If a Daily Measurement is out-of-range, the device will report the information in the programmer's system summary. In order for an alert to be declared when an out-of-range Daily Measurement is detected, the Daily Measurements must be activated in the device **and** the LATITUDE Alerts must be configured On, as described below.

1. Program device.

































Within the programmer's Summary – Lead Status Setup screen, physicians can individually program Daily Measurements to On or Off.

2. Configure LATITUDE Alerts.

Within the LATITUDE clinician website, navigate to the Configure tab to select alerts at the clinic or physician level. To select alerts at the patient level, navigate to the Configure Patient tab.

- From the Yellow Alert Settings page, individually select desired yellow alerts.
- From the Schedule page, set-up the remote follow-up schedule (e.g., once every three months) and the between follow-up data collection schedule (e.g., weekly, patient initiated).

Appendix A. List of LATITUDE Alerts by CRT-D and ICD Family

<p>KEY</p> <p> Yellow Alert (Configurable, select On or Off)</p> <p> Red Alert (Not Configurable, always On)</p> <p> Alert is available but limit (if applicable) is not programmable.</p> <p>(20 Ω) Nominal Limit</p> <p>N/A Alert is NOT available</p>		<p>COGNIS[®]100-D RF HE Models P106/P107/P108</p>	<p>PUNCTUA[™] / ENERGEN[™] INCEPTA[™] RF HE CRT-Ds Models P052/P142/P143 P162/P163/P165</p>	<p>TELIGEN[®]100 VR RF HE Model F102/F103</p>	<p>TELIGEN[®]100 DR RF HE Model F110/F111</p>	<p>PUNCTUA[™] / ENERGEN[™] INCEPTA[™] - VR RF HE ICDs Models F050/F140/F141 F160/F161</p>	<p>PUNCTUA[™] / ENERGEN[™] INCEPTA[™] - DR RF HE ICDs Models F052/F142/F143 F162/F163</p>
Battery	 Voltage was too low for projected remaining capacity	■	■	■	■	■	■
	 Explant indicator reached	■	■	■	■	■	■
	 Remote monitoring disabled due to limited battery capacity	■	■	■	■	■	■
Shock Lead	 Low shock lead impedance detected when attempting to deliver a shock*	■	■	■	■	■	■
	 High shock lead impedance detected when attempting to deliver a shock*	■	■	■	■	■	■
Tachy Mode	 V-Tachy Mode set to value other than Monitor + Therapy†	■	■	■	■	■	■
Pacing	 Right ventricular pacing	N/A	N/A	■	■	■	■
	 Cardiac Resynchronization Therapy pacing	■	■	N/A	N/A	N/A	N/A
Arrhythmias	 Shock therapy delivered to convert arrhythmia (Ventricular)	■	■	■	■	■	■
	 Accelerated arrhythmia episode (Ventricular)	■	■	■	■	■	■
	 Atrial Arrhythmia Burden in a 24 hour period	■	■	N/A	■	N/A	■
	 Patient triggered event stored	■	■	■	■	■	■
Other	 High voltage detected on shock lead during charge*	■	■	■	■	■	■
	 Therapy history corruption detected*	■	■	■	■	■	■
	 Possible device malfunction*	■	■	■	■	■	■
	 Device parameter error*	■	■	■	■	■	■
Weight	 Weight gain of at least 2.27 kg in a week or at least 0.91 kg average over a two or more day period‡	■	■	■	■	■	■
	 Weight loss of at least 2.27 kg in a week or at least 0.91 kg average over a two or more day period‡	■	■	■	■	■	■
Daily Measurements	 Low shock lead impedance*	(20 Ω)	(20 Ω)	(20 Ω)	(20 Ω)	(20 Ω)	(20 Ω)
	 High shock lead impedance*	(125 Ω)	(125 Ω)	(125 Ω)	(125 Ω)	(125 Ω)	(125 Ω)
	 Low right ventricular pacing lead impedance*	(200 Ω)	(200 Ω)	(200 Ω)	(200 Ω)	(200 Ω)	(200 Ω)
	 High right ventricular pacing lead impedance*	(2000 Ω)	(2000 Ω)	(2000 Ω)	(2000 Ω)	(2000 Ω)	(2000 Ω)
	 Low right ventricular intrinsic amplitude*	(3 mV)	(3 mV)	(3 mV)	(3 mV)	(3 mV)	(3 mV)
	 Low left ventricular intrinsic amplitude*	(3 mV)	(3 mV)	N/A	N/A	N/A	N/A
	 Low left ventricular pacing lead impedance*	(200 Ω)	(200 Ω)	N/A	N/A	N/A	N/A
	 High left ventricular pacing lead impedance*	(2000 Ω)	(2000 Ω)	N/A	N/A	N/A	N/A
	 Low atrial intrinsic amplitude*	(0.5 mV)	(0.5 mV)	N/A	(0.5 mV)	N/A	(0.5 mV)
	 Low atrial pacing lead impedance*	(200 Ω)	(200 Ω)	N/A	(200 Ω)	N/A	(200 Ω)
	 High atrial pacing lead impedance*	(2000 Ω)	(2000 Ω)	N/A	(2000 Ω)	N/A	(2000 Ω)

*LATITUDE will provide one alert notification the first time the device/lead condition occurs. LATITUDE notification for a new occurrence of the same condition (high or low) will not occur until the clinical event is reset in the implanted device at an in-clinic programmer follow-up.

†LATITUDE will provide one alert notification the first time it detects that the V-Tachy mode has been changed from Monitor + Therapy. LATITUDE notification for a new occurrence will not occur until the V-Tachy Mode value is programmed to Monitor + Therapy in the implanted device at in in-clinic programmer follow-up.

‡Available for patient's with LATITUDE weight scales.