

LATITUDE[®] Alerts (Clinical Event Notifications)

SUMMARY

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

For patients enrolled in LATITUDE, remote monitoring can be performed daily (wireless only) or weekly, during scheduled remote follow-up visits, and during patient-initiated interrogations.

Once data is collected in the patient's home (via the Communicator), a patient's device data and relevant health information are available from the secure LATITUDE clinician website.

The LATITUDE system can be configured to send red and yellow 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 family.
- Appendix B provides a list of LATITUDE Alerts by ICD family.

CRM PRODUCTS REFERENCED*

See Appendix A and B

LATITUDE Patient Management System

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

CRM CONTACT INFORMATION

Technical Services – U.S.
1.800.CARDIAC (227.3422)
Tech.Services@bsci.com

Technical Services – Europe
+32 2 416 7222
eurtechservice@bsci.com

LATITUDE Clinician Support
1.800.CARDIAC (227.3422)
latitude@bsci.com

Patient Services
1.866.484.3268 – U.S. and Canada
001.651.582.4000 – International

LATITUDE[®] Alerts are designed to provide device following physicians (typically electrophysiologists) and 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 are categorized as red or yellow.

Red Alerts

Red alerts are declared when conditions are detected that could potentially leave the patient without available device therapy. The LATITUDE system is designed to notify clinicians within 24 hours if a red alert is detected by the communicator. Although red alerts cannot be deselected (i.e., configured Off) in the LATITUDE system, several notification preferences can be customized. To customize notification preferences, physicians should contact their local sales representative or LATITUDE Clinician Support and complete a Red Alert Notification Form.

NOTE: During remote device interrogations, red alert conditions present in 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 the following:

- Notification is optional. Yellow alerts are individually selectable; a physician may choose to receive all, some, or no yellow alerts.
- Yellow alerts may be received via the LATITUDE website and optionally via fax machine.

Daily Measurement Alerts

Intrinsic amplitude and lead impedance are measured daily by the implanted device (in most device families—see Appendices A and B). If a Daily Measurement is out-of-range, the device will report a clinical event in the programmer's System Summary screen. 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 Daily Measurement Setup screen, physicians can individually program Daily Measurements to On or Off, as well as program the Daily Measurement limits that trigger a Clinical Event (in some device families, see Appendices A and B).

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 Family

KEY		CONTAK CD 2 / 2 HE Models H115/H119	CONTAK RENEWAL® Model H135	RENEWAL 3 / 3 HE/3 RF/3 RF HE Models H170/H175/H177 H179/H210/H215/H217/H219	LIVIAN™ RF / RF HE Models H220/H225/H227/H229	COGNIS™ 100-D RF HE Model N118/N119
	Yellow Alert (Configurable, select On or Off)					
	Red Alert (Not Configurable, always On)					
■	Alert is available but limit (if applicable) is not programmable.					
20-125 Ω	Alert is available and programmable. Program limit in implanted device (between values listed).					
(20 Ω)	Nominal Limit					
N/A	Alert is NOT available					
Battery	 Device battery has reached Elective Replacement Indicator (ERI)	■	■	■	■	N/A
	 Device battery has reached End of Life (EOL)	■	■	■	■	N/A
	 Voltage was too low for projected remaining capacity	N/A	N/A	N/A	N/A	■
	 Explant indicator reached	N/A	N/A	N/A	N/A	■
	 Remote monitoring disabled due to limited battery capacity	N/A	N/A	N/A	N/A	■
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 changed due to magnet	■	■	■	N/A	N/A
	 V-Tachy Mode set to value other than Monitor + Therapy	■	■	■	■	■
Pacing	 Right Ventricular Pacing*	■	N/A	N/A	N/A	N/A
	 Cardiac Resynchronization Therapy Pacing	N/A	■	■	■	■
Arrhythmias	 Shock therapy delivered to convert arrhythmia (Ventricular)	■	■	■	■	■
	 Accelerated arrhythmia episode (Ventricular)	■	■	■	■	■
	 Atrial Arrhythmia Burden in a 24 Hour Period	■	■	■	■	■
	 Patient triggered event stored	N/A	N/A	■	■	■
Other	 High Voltage Detected on Shock Lead During Charge	■	■	■	■	■
	 Therapy history corruption detected	N/A	N/A	N/A	N/A	■
	 Possible Device Malfunction	■	■	■	■	■
	 Device Parameter Error	■	■	■	■	■
Weight	 Weight gain of at least 5 lb. in a week or at least 2 lb. average over a two or more day period	■	■	■	■	■
	 Weight loss of at least 5 lb. in a week or at least 2 lb. average over a two or more day period	■	■	■	■	■

*CONTAK CD 2 has RV pacing alert available but not CRT pacing alert, due to differences in how the device accomplishes LV Pacing.

Appendix A. List of LATITUDE Alerts by CRT-D Family, Continued

KEY		CONTAK CD 2 / 2 HE Models H115/H119	CONTAK RENEWAL® Model H135	RENEWAL 3 / 3 HE / 3 RF / 3 RF HE Models H170 / H175 / H177 / H179 / H210 / H215 / H217 / H219	LIVANT™ RF / RF HE Models H220 / H225 / H227 / H229	COGNIS™ 100-D RF HE Model N118 / N119
	Yellow Alert (Configurable, select On or Off)					
	Red Alert (Not Configurable, always On)					
■	Alert is available but limit (if applicable) is not programmable.					
20-125 Ω	Alert is available and programmable. Program limit in implanted device (between values listed).					
(20 Ω)	Nominal Limit					
N/A	Alert is NOT available					
Daily Measurements	 Low shock lead impedance [†]	■ (20 Ω)	■ (20 Ω)	■ (20 Ω)	■ (20 Ω)	■ (20 Ω)
	 High shock lead impedance [†]	■ (125 Ω)	■ (125 Ω)	■ (125 Ω)	■ (125 Ω)	■ (125 Ω)
	 Low right ventricular pacing lead impedance	N/A	N/A	■ (200 Ω)	■ (200 Ω)	■ (200 Ω)
	 High right ventricular pacing lead impedance	N/A	N/A	■ (2500 Ω)	■ (2500 Ω)	■ (2000 Ω)
	 Low right ventricular intrinsic amplitude	N/A	N/A	■ (3 mV)	■ (3 mV)	■ (3 mV)
	 High right ventricular intrinsic amplitude [‡]	N/A	N/A	■ (25 mV)	■ (25 mV)	N/A
	 Low left ventricular intrinsic amplitude	N/A	N/A	■ (3 mV)	■ (3 mV)	■ (3 mV)
	 High left ventricular intrinsic amplitude [‡]	N/A	N/A	■ (25 mV)	■ (25 mV)	N/A
	 Low left ventricular pacing lead impedance	N/A	N/A	■ (100 Ω)	■ (100 Ω)	■ (200 Ω)
	 High left ventricular pacing lead impedance	N/A	N/A	■ (2000 Ω)	■ (2000 Ω)	■ (2000 Ω)
	 Low atrial intrinsic amplitude	N/A	N/A	■ (0.5 mV)	■ (0.5 mV)	■ (0.5 mV)
	 High atrial intrinsic amplitude [‡]	N/A	N/A	■ (25 mV)	■ (25 mV)	N/A
	 Low atrial pacing lead impedance	N/A	N/A	■ (200 Ω)	■ (200 Ω)	■ (200 Ω)
	 High atrial pacing lead impedance	N/A	N/A	■ (2500 Ω)	■ (2500 Ω)	■ (2000 Ω)

[†]CONTAK CD 2 and CONTAK RENEWAL (Model H135) perform daily shock lead impedance tests, but the results are not trended. If two consecutive out of range measurements occur, a clinical event is triggered in the device, which can trigger a subsequent LATITUDE red alert.

[‡]COGNIS does not have an upper limit for intrinsic amplitude measurements. Even though the LATITUDE system allows you to configure this alert to On, an out-of-range indicator must be declared by the implanted device in order to generate an alert. Because no upper limit exists, high intrinsic amplitude yellow alerts will not be generated.

Appendix B. List of LATITUDE Alerts by ICD Family

KEY		VENTAK PRIZM® VR / VR HE Models 1850/1852/1857	VENTAK PRIZM DR / DR HE Models 1851/1853/1858	VENTAK PRIZM 2 VR Model 1860	VENTAK PRIZM 2 DR Model 1861	VITALITY® DS VR Model TT135	VITALITY DS DR / EL DR Model TT125/TT127	VITALITY 2 VR / 2 EL VR Model TT175/TT177	VITALITY 2 DR / 2 EL DR Model TT165/TT167	VITALITY DR HE Model TT180	CONFIDENT™ DR RF HE Models E030	TELIGEN™ 100 VR RF HE Model E102	TELIGEN™ 100 DR RF HE Model E110
Battery	Device battery has reached Elective Replacement Indicator (ERI)	■	■	■	■	■	■	■	■	■	■	N/A	N/A
	Device battery has reached End of Life (EOL)	■	■	■	■	■	■	■	■	■	■	N/A	N/A
	Voltage was too low for projected remaining capacity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	■	■
	Explant indicator reached	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	■	■
	Remote monitoring disabled due to limited battery capacity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	■	■
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 changed due to magnet	■	■	■	■	■	■	N/A	N/A	N/A	N/A	N/A	N/A
	V-Tachy Mode set to value other than Monitor + Therapy	■	■	■	■	■	■	■	■	■	■	■	■
Pacing	Right Ventricular Pacing	■	■	■	■	■	■	■	■	■	■	■	■
Arrhythmias	Shock therapy delivered to convert arrhythmia (Ventricular)	■	■	■	■	■	■	■	■	■	■	■	■
	Accelerated arrhythmia episode (Ventricular)	■	■	■	■	■	■	■	■	■	■	■	■
	Atrial Arrhythmia Burden in a 24 Hour Period	N/A	■	N/A	■	N/A	■	N/A	■	■	■	N/A	■
	Patient triggered event stored	N/A	N/A	■	■	■	■	■	■	■	■	■	■
Other	High Voltage Detected on Shock Lead During Charge	■	■	■	■	■	■	■	■	■	■	■	■
	Therapy history corruption detected	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	■	■
	Possible Device Malfunction	■	■	■	■	■	■	■	■	■	■	■	■
	Device Parameter Error	■	■	■	■	■	■	■	■	■	■	■	■

Appendix B. List of LATITUDE Alerts by ICD Family, Continued

KEY		VENTAK PRIZM® VR / VR HE Models 1850/1852/1857	VENTAK PRIZM DR. / DR HE Models 1851/1853/1858	VENTAK PRIZM 2 VR Model 1860	VENTAK PRIZM 2 DR Model 1861	VITALITY® DS VR Model T135	VITALITY DS DR / EL DR Model T125/T127	VITALITY 2 VR / 2 EL VR Model T175/T177	VITALITY 2 DR / 2 EL DR Model T165/ T167	VITALITY DR HE Model T180	CONFIENT™ DR RF HE Models E030	TELIGEN™100 VR RF HE Model E102	TELIGEN™100 DR RF HE Model E110
Weight	Weight gain of at least 5 lb. in a week or at least 2 lb. average over a two or more day period	■	■	■	■	■	■	■	■	■	■	■	■
	Weight loss of at least 5 lb. in a week or at least 2 lb. average over a two or more day period	■	■	■	■	■	■	■	■	■	■	■	■
Daily Measurement	Low shock lead impedance [†]	■ (20 Ω)	■ (20 Ω)	20–125 Ω (20 Ω)	20–125 Ω (20 Ω)	20–125 Ω (20 Ω)	20–125 Ω (20 Ω)	20–125 Ω (20 Ω)	20–125 Ω (20 Ω)	■ (20 Ω)	■ (20 Ω)	■ (20 Ω)	■ (20 Ω)
	High shock lead impedance [†]	■ (125 Ω)	■ (125 Ω)	20–125 Ω (80 Ω)	20–125 Ω (80 Ω)	20–125 Ω (125 Ω)	20–125 Ω (125 Ω)	20–125 Ω (125 Ω)	20–125 Ω (125 Ω)	■ (125 Ω)	■ (125 Ω)	■ (125 Ω)	■ (125 Ω)
	Low right ventricular pacing lead impedance	N/A	N/A	250–2500 Ω (250 Ω)	250–2500 Ω (250 Ω)	250–2500 Ω (250 Ω)	250–2500 Ω (250 Ω)	250–2500 Ω (250 Ω)	250–2500 Ω (250 Ω)	■ (200 Ω)	■ (200 Ω)	■ (200 Ω)	■ (200 Ω)
	High right ventricular pacing lead impedance	N/A	N/A	250–2500 Ω (2500 Ω)	250–2500 Ω (2500 Ω)	250–2500 Ω (2500 Ω)	250–2500 Ω (2500 Ω)	250–2500 Ω (2500 Ω)	250–2500 Ω (2500 Ω)	■ (2500 Ω)	■ (2500 Ω)	■ (2000 Ω)	■ (2000 Ω)
	Low right ventricular intrinsic amplitude	N/A	N/A	0.3–25 mV (3 mV)	0.3–25 mV (3 mV)	0.3–25 mV (3 mV)	0.3–25 mV (3 mV)	0.3–25 mV (3 mV)	0.3–25 mV (3 mV)	■ (3 mV)	■ (3 mV)	■ (3 mV)	■ (3 mV)
	High right ventricular intrinsic amplitude [†]	N/A	N/A	0.3–25 mV (25 mV)	0.3–25 mV (25 mV)	0.3–25 mV (25 mV)	0.3–25 mV (25 mV)	0.3–25 mV (25 mV)	0.3–25 mV (25 mV)	■ (25 mV)	■ (25 mV)	N/A	N/A
	Low atrial intrinsic amplitude	N/A	N/A	N/A	0.3–25 mV (1 mV)	N/A	0.3–25 mV (1 mV)	N/A	0.3–25 mV (1 mV)	■ (0.5 mV)	■ (0.5 mV)	N/A	■ (0.5 mV)
	High atrial intrinsic amplitude [†]	N/A	N/A	N/A	0.3–25 mV (25 mV)	N/A	0.3–25 mV (25 mV)	N/A	0.3–25 mV (25 mV)	■ (25 mV)	■ (25 mV)	N/A	N/A
	Low atrial pacing lead impedance	N/A	N/A	N/A	250–2500 Ω (250 Ω)	N/A	250–2500 Ω (250 Ω)	N/A	250–2500 Ω (250 Ω)	■ (200 Ω)	■ (200 Ω)	N/A	■ (200 Ω)
High atrial pacing lead impedance	N/A	N/A	N/A	250–2500 Ω (2500 Ω)	N/A	250–2500 Ω (2500 Ω)	N/A	250–2500 Ω (2500 Ω)	■ (2500 Ω)	■ (2500 Ω)	N/A	■ (2000 Ω)	

[†]TELIGEN does not have an upper limit for intrinsic amplitude measurements. Even though the LATITUDE system allows you to configure this alert to On, an out-of-range indicator must be declared by the implanted device in order to generate an alert. Because no upper limit exists, high intrinsic amplitude yellow alerts will not be generated.