

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 at scheduled intervals.

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

Once data is collected via the patient's Communicator and sent to LATITUDE, device data and relevant health information are available from the secure LATITUDE 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

The following are trademarks of Cardiac Pacemakers Inc., a Boston Scientific company: LATITUDE Patient Management System; See Appendices A & B for LATITUDE enabled ICDs and CRT-Ds.

Products referenced herein are identified by trademarks of Cardiac Pacemakers Inc., a Boston Scientific company, and may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator

ICD: Implantable Cardioverter Defibrillator

CRM CONTACT INFORMATION

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International LATITUDE Customer Support

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LATITUDE® Alerts are designed to provide device following physicians (typically electrophysiologists) and health following physicians (typically cardiologists or heart failure specialists) with 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 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 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 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 (in most device families—see Appendices A and B). 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 Daily Measurement Setup screen (for COGNIS® and TELIGEN® the Summary - Lead Status 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 Models N118/N119
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 ^a	N/A ^a	N/A	N/A
	V-Tachy Mode set to value other than Monitor + Therapy	■	■	■	■	■
Pacing	Right Ventricular Pacing	■ ^b	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 ^c	■	■	■	■	■
	Weight loss of at least 5 lb. in a week or at least 2 lb. average over a two or more day period ^c	■	■	■	■	■

^aCONTAK RENEWAL (Model H135) and RENEWAL 3 devices no longer have the Change Tachy Mode with Magnet feature available, therefore no "V-Tachy Mode changed due to Magnet" red alerts will be generated.

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





















^cThis alert is only available if the patient has a LATITUDE weight scale.

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	LIVIAN RF / RF HE Models H220/H225/H227/H229	COGNIS 100-D RF HE Models N18/N19
	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	■ ^d (20 Ω)	■ ^d (20 Ω)	■ (20 Ω)	■ (20 Ω)	■ (20 Ω)
	 High shock lead impedance	■ ^d (125 Ω)	■ ^d (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)










^dCONTAK 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.

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 Models TT125/TT127	VITALITY 2 VR / 2 EL VR Models TT175/TT177	VITALITY 2 DR / 2 EL DR Models TT165/TT167	VITALITY DR HE Model TT180	CONFIENT® DR RF HE Models E030	TELIGEN 100 VR RF HE Model E102	TELIGEN 100 DR RF HE Model E110
	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	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	■	■	■	■	■	■	■	■	■	■	■	■

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

KEY													
	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												
		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 Models T175/T177	VITALITY 2 DR / 2 EL DR Models T165/T167	VITALITY DR HE Model T180	CONFIDENT DR RF HE Model 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 ^e	■	■	■	■	■	■	■	■	■	■	■	■
	 Weight loss of at least 5 lb. in a week or at least 2 lb. average over a two or more day period ^e	■	■	■	■	■	■	■	■	■	■	■	■
Daily Measurements	 Low shock lead impedance	■ ^f (20 Ω)	■ ^f (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	■ ^f (125 Ω)	■ ^f (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)

^eThis alert is only available if the patient has a LATITUDE weight scale.

^fPRIZM VR and PRIZM DR 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.