SUMMARY

Boston Scientific's LATITUDE™ NXT Patient Management System enables a clinician to periodically monitor patient and device information remotely via a Communicator placed in the patient's home. The clinician can review this information on the LATITUDE NXT website[1] to supplement in-clinic visits.

The LATITUDE NXT system generates alerts for a number of conditions. Alerts are designed to notify the clinician of potential health problems or device clinical events but are not intended to be used as the sole basis for making decisions about patient care.

Products Referenced

LATITUDE NXT Patient Management System
Pacing and Defibrillation Products Supported by LATITUDE NXT

For comprehensive information on device operation, reference the full instructions for use found at: **www.bostonscientific-elabeling.com**.
CAUTION: The law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

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LATITUDE™ NXT Alerts

The LATITUDE Communicator, positioned in the patient's home, periodically collects data from the implanted device and from the optional weight scale and blood pressure monitor, and transmits it to a secure LATITUDE NXT website[1] for clinician review. Data are collected by the LATITUDE NXT system as scheduled by the clinic. Sources of data are as follows:

- Some types of data are ***automatically*** measured by the implanted device and are then made available for collection by the LATITUDE Communicator. For example, battery status is automatically measured by the device throughout its life.
- Other data can also be collected daily by the implanted device when programmed to do so by the clinician. For example, when 'Daily Measurements' are programmed On, lead impedance, intrinsic amplitude, and threshold measurements are performed and available for upload into the LATITUDE NXT system. ***NOTE****: Most Daily Measurements are nominally On.*
- Data from the optional home health monitoring equipment (weight and blood pressure measurements) is transmitted to the patient's Communicator via a wireless connection.

Alerts

Clinicians can review the remotely collected data on the LATITUDE NXT website at their convenience. However, the LATITUDE NXT system will also generate "alert notifications" for a number of potential patient health problems or implanted device clinical events. Alert conditions may be detected during daily alert interrogations, weekly alert interrogations[2], remote scheduled follow-up interrogations, and patient-initiated interrogations. The LATITUDE NXT system notifies the patient's clinicians via the LATITUDE NXT website of any detected alert conditions. Additional alert notifications are also available via text and email messages (see ***Alert Notes***).

There are two levels of alert conditions: red alerts and yellow alerts.

Red Alerts

Red alerts are declared when conditions are detected within the implanted device that could potentially leave the patient without device therapy. They are provided to clinicians in the Primary Patient Group[3] via the LATITUDE NXT website if the Communicator reports that an alert condition has been detected. To receive red alerts, the clinician must log onto the LATITUDE NXT website and review the View Patient List page. If the Communicator is unable to connect and transfer the red alert data within 24 hours, an indicator is illuminated on the Communicator directing the patient to call for further instructions.

1 The LATITUDE NXT website was developed to support Internet Explorer, Mozilla Firefox, and Apple Safari on the Mac, iPad, and iPhone web browsers. The website may not function properly when using browser versions that were subsequently released. Call LATITUDE Customer Support for a list of supported web browsers.

2 Availability dependent on type of implanted device and model of Communicator.

3 Each LATITUDE NXT patient can be associated with up to two different clinics or two different patient groups in one clinic (primary or secondary). The primary clinic /patient group is typically responsible for monitoring a patient's device, including regularly scheduled device follow-ups. This clinic is also responsible for managing red alerts detected when the patient's implanted device is interrogated. The primary clinic is also responsible for managing yellow alerts if notification has been configured. All LATITUDE NXT patients must have an assigned primary clinic in order to be monitored.

NOTE*: Patient Groups provide default alert and schedule configuration settings for associated patients. A patient can have customized settings that differ from the Patient Group default settings.*

Yellow Alerts

Yellow alert notifications are declared when a certain device condition or patient heart-health issue is detected that may warrant clinician review or investigation. Yellow alert notification preferences can be configured by the clinician to ON or OFF. Clinicians may receive all, some, or no yellow alerts. Yellow alerts are provided and accessed through the LATITUDE™ NXT website. For complete instructions on configuring yellow alerts, reference the LATITUDE NXT Patient Management Clinician Manual. For a complete listing of Alerts, reference Tables 1 and 2.

Alert Notes

- In addition to website review, secondary alert notification is available through text and email messages. These reminders can be configured for red alerts only, yellow alerts only or red and yellow alerts, but only at the Patient Group Level. The clinician can have alert messages sent 24 hours, 7 days a week or Monday through Friday from 8AM to 5PM. Although secondary notification through email and SMS text messages is available[4], these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the LATITUDE NXT website.
- Alerts are an indicator that further investigation may be appropriate, but are not intended for use as the sole basis for making decisions about patient medical care.
- Alerts can be verified by viewing information on the LATITUDE NXT website and/or by reviewing diagnostic information from the implanted device during an in-clinic interrogation using a programmer.
- Most Daily Measurements are nominally On within the implanted device. However, if these features are programmed Off within the implanted device, the LATITUDE NXT system will ***not*** generate an alert for an event even if the LATITUDE alert is configured On. The implanted device must first measure, record, and detect data as out of range before the LATITUDE NXT system will detect and generate a red or yellow alert.
- If, during self-monitoring, an implanted Boston Scientific device detects certain device and/or lead conditions, a clinical event or status message will be triggered for that condition(s) and subsequent interrogation by a PRM will display either a clinical event and/or status message to alert the user. If the condition is still present when LATITUDE/NXT completes a remote interrogation, and the alert is configured On, then the condition will be displayed as a status message and/or will trigger a corresponding red or yellow alert.
- The LATITUDE NXT system does not provide continuous monitoring. As a remote monitoring system, the LATITUDE NXT system provides periodic patient monitoring as configured by the clinician. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of device and patient information as intended by the clinician. For a complete list of system limitations, reference the LATITUDE Patient Management Clinician Manual.

4 SMS text alerts are not available in Japan.

Table 1. LATITUDE™ NXT Alerts for Pacemakers, ICDs, CRT-Ds, and CRT-Ps

Grouping	Alert	Pace-maker	CRT-P	ICD	CRT-D	Configurable via LATITUDE System(Nominal)	Programmable Limit via Model 3120 programmer (Nominal)
Battery	Remote monitoring disabled due to limited battery capacity	✔	✔	✔	✔	ON	
	Voltage was too low for projected remaining capacity [5]	✔	✔	✔	✔	ON	
	Explant indicator reached [5]	✔	✔	✔	✔	ON, OFF (ON)	
Right Ventricular LATITUDE Lead Check+™	Shock lead impedance out of range [5]			✔	✔	ON	Low (≤20 Ω) [15, 16] High 125-200 Ω (≥125 Ω)[15, 16]
	Low shock lead impedance detected when attempting to deliver a shock [5]			✔	✔	ON	
	High shock lead impedance detected when attempting to deliver a shock [5]			✔	✔	ON	
	Right ventricular or single chamber pacing lead impedance out of range [5, 6]	✔	✔	✔	✔	ON	Low 200-500 Ω (≤200 Ω) [15, 16, 17. 18] High (≥2000 Ω) [17] High 2000-2500 Ω (≥2000 Ω) [15] High 2000-3000 Ω (≥2000 Ω) [16, 18]
	Right ventricular pacing lead impedance abrupt change [7, 8]			✔	✔	ON, OFF (OFF)	
	Right ventricular non-physiologic signal detected [8]			✔	✔	ON, OFF (OFF)	
	Right ventricular or single chamber intrinsic amplitude out of range [5, 6]	✔	✔	✔	✔	ON, OFF (ON)	Low (≤3.0 mV) or (≤0.5 mV)
	Right ventricular automatic threshold detected as > programmed amplitude or suspended [5, 9]	✔	✔	✔	✔	ON, OFF (ON)	
Left Ventricular Pacing Leads	Left ventricular intrinsic amplitude out of range [5]		✔		✔	ON, OFF (ON)	Low (≤3.0 mV)
	Left ventricular pacing lead impedance out of range [5]		✔		✔	ON, OFF (ON)	Low 200-500 Ω (≤200 Ω) [15, 16, 17,18] High (≥2000 Ω) [17] High 2000-2500 Ω (≥2000 Ω) [15] High 2000-3000 Ω (≥2000 Ω) [16,18]
	Left ventricular automatic threshold detected as > programmed amplitude or suspended [5, 10]				✔	ON, OFF (ON)	
Atrial Pacing Leads	Atrial intrinsic amplitude out of range [5]	✔	✔	✔	✔	ON, OFF (ON)	Low (≤0.5 mV)
	Atrial pacing lead impedance out of range [5, 11]	✔	✔	✔	✔	ON, OFF (ON)	Low 200-500 Ω (≤200 Ω)[15, 16, 17, 18] High (≥2000 Ω)[17] High 2000-2500 Ω (≥2000 Ω)[15] High 2000-3000 Ω (≥2000 Ω)[16, 18]
	Atrial automatic threshold detected as > programmed amplitude or suspended [5, 11, 12]	✔	✔	✔	✔	ON, OFF (ON)	
Tachy Mode/ Therapy	V-Tachy Mode set to value other than Monitor + Therapy [13]			✔	✔	ON	
Arrhythmias	Ventricular shock therapy delivered to convert arrhythmia			✔	✔	ON, OFF (ON)	
	Antitachycardia pacing (ATP) therapy delivered to convert arrhythmia			✔	✔	ON, OFF (ON)	
	Accelerated ventricular arrhythmia episode			✔	✔	ON, OFF (ON)	
	VT Episodes (V>A) [14]	✔	✔			ON, OFF (ON)	
	Atrial Arrhythmia burden of at least {> 0, 0.5, 1, 3, 6, 12, 18, or 24} hours in a 24 hour period [7, 14]	✔	✔	✔	✔	ON, OFF (ON) (If ON > 0 hours in a 24 hour period)	
	Patient triggered event stored	✔	✔	✔	✔	ON, OFF (ON)	
	Nonsustained ventricular arrhythmia episode(s)	✔	✔	✔	✔	ON, OFF (OFF)	
HeartLogic™ [20]	HeartLogic Index at or above {2,4,6,8,10,12,14,16,18,20,22,24,26,28,30,32,34,36,38,40}[19] Perform daily interrogations until condition is resolved {On/Off}			✔	✔	ON (16) OFF	
Pacing	Cardiac Resynchronization Therapy pacing of < {50, 60, 70, 80, 90, or 95} %		✔		✔	ON, OFF (OFF) (If ON, 80%)	
	Right ventricular pacing of > {10, 20, 30, 40, or 50} % [14]	✔		✔		ON, OFF (OFF) (If ON, 40%)	
Others	Possible device malfunction [5]	✔	✔	✔	✔	ON	
	High voltage detected on shock lead during charge [5]			✔	✔	ON	
	Device in Safety Mode [5, 16, 17, 18]	✔	✔	✔	✔	ON	
	Device in Electrocautery Protection Mode [5]	✔	✔			ON	
	Device Brady Mode Off [13]	✔	✔			ON, OFF (ON)	
	Therapy history corruption detected [5]	✔	✔	✔	✔	ON, OFF (ON)	
	Weight gain of at least {0.45, 0.911, 1.36, 1.81, 2.27, 2,72, 3.18, 3.63, 4.08, or 4.54} kg(s) or {1, 2, 3, 4, 5, 6, 7, 8, 9, or 10} lb(s) in {1-7} day(s)	✔	✔	✔	✔	ON, OFF (OFF) (If ON,2.27 kgs / 5 lbs, 7 days)	
	Signal Artifact Monitor (SAM) device diagnostic	✔	✔			ON, OFF (ON[21], OFF[22])	

Table 2. LATITUDE™ NXT Alerts for the EMBLEM™ S-ICD

Grouping	Alert	Configurable via LATITUDE System (Nominal)
S-ICD	Device battery has reached End of Life (EOL)	ON
	High Electrode Impedance [5]	ON
	Therapy Off	ON
	Possible device malfunction [5]	ON
	Device battery has reached Elective Replacement Indicator (ERI)	ON, OFF (ON)
	Shock therapy delivered to convert arrhythmia	ON, OFF (ON)
	Untreated episode	ON, OFF (ON)
	Sensing not fully optimized	ON, OFF (ON)
	Measured AF of at least {> 0, 0.5, 1, 3, 6, or 12} hours in a 24 hour period (A219 only)	ON, OFF (ON) (If ON > 0 hours in a 24 hour period)
	Weight gain of at least {0.45, 0.911, 1.36, 1.81, 2.27, 2,72, 3.18, 3.63, 4.08, or 4.54} kg(s) or {1, 2, 3, 4, 5, 6, 7, 8, 9, or 10} lb(s) in {1-7} day(s)	ON, OFF (OFF) (If ON - 2.27 kgs /5 lbs, 7 days)

Tables 1 and 2. LATITUDE™ NXT Alerts Footnotes

5 The LATITUDE NXT system sends one notification for an alert condition detected by the system. It does not repeat alert notifications for the same condition unless the condition is cleared/reset with a programmer and then reoccurs during a following data collection activity.

6 For single-chamber devices, the amplitude values reported and out of range limits applied correspond to the selected lead position and programmed Brady Mode.

7 If more than 14 days elapse between alert checks, some data may not be assessed for this alert condition.

8 Alert is only available for ICDs and CRT-Ds (Table 2) with Wave™ Communicator Models 6498, 6280, 6290, and 6288.

9 Alert is only available for devices with the Right Ventricular Automatic Threshold feature, which include: ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™, VISIONIST™, ADVANTIO™, INGENIO™, VITALIO™, FORMIO™, INVIVE™, INTUA™, INLIVEN™, AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™.

10 Alert is only available for devices with the Left Ventricular Automatic Threshold Feature, which include: VISIONIST™, AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, and MOMENTUM™.

11 Alert is not available for Models J178 and K188.

12 Alert is only available for devices with the Right Atrial Automatic Threshold feature, which include: ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™, VISIONIST™, VITALIO™, FORMIO™, INTUA™, INLIVEN™, AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™.

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

14 Alert is not available for SSI devices.

15 Applies to PUNCTUA™, ENERGEN™, INCEPTA™, COGNIS™ and TELIGEN™ families of ICDs and CRT-Ds.

16 Applies to ORIGEN™, INOGEN™, DYNAGEN™, AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™ families of ICDs and CRT-Ds.

17 Applies to ADVANTIO™, INGENIO™, VITALIO™, FORMIO™, INVIVE™, INTUA™ and INLIVEN™ families of pacemakers and CRT-Ps.

18 Applies to ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™, and VISIONIST™ families of pacemakers and CRT-Ps.

19 The LATITUDE NXT system will issue a re-alert if the patient is still in the alert state 7 days after the previous alert. The re-alerts will continue as long as the patient is in the alert state. The re-alert capability is automatic and is not user controlled. If a clinician wants to stop the re-alerting for a specific patient they need to either adjust the threshold, or turn the alert off.

20 HeartLogic™ is available with a subscription in RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™ families of ICDs and CRT-Ds.

21 Applies to new clinics added to LATITUDE NXT as of January 25, 2020

22 Applies to existing clinics on LATITUDE NXT prior to January 25, 2020

Products Referenced

The following device families/models are supported by the LATITUDE NXT system. Not all devices are approved and/or market-released in all geographies. Please contact Boston Scientific Technical Services or LATITUDE Customer Support for information regarding a specific device model and/or geographic location.

Table 3. Pacing and Defibrillation Products Supported by LATITUDE NXT

Device Type	Device Family	Model Numbers
Pacemakers	ESSENTIO™	L110 L111 L131
	PROPONENT™	L200 L201 L209 L210 L211 L221 L231
	ACCOLADE™	L300 L301 L310 L311 L321 L331
	ADVANTIO™	J062 J063 J064 J065 J066 J067 K062 K063 K064 K082 K083 K084 K085 K086 K087
	INGENIO™	J172 J173 J174 J175 J176 J177 J178 J179 K172 K173 K174 K182 K183 K184 K185 K186 K187 K188 K189
	VITALIO™	J272 J273 J274 J275 J276 J277 K272 K273 K274 K275 K277 K282 K283 K284 K285 K286 K287
	FORMIO™	J278 J279 K278 K288 K289
CRT-Ps	VALITUDE™	U125 U128
	VISIONIST™	U225 U226 U228
	INVIVE™	V172 V173 V182 V183 W172 W173
	INTUA™	V272 V273 V282 V283 W272 W273
	INLIVEN™	V284 V285 W274 W275
ICDs	ORIGEN™	D000 D001 D002 D003 D050 D051 D052 D053
	INOGEN™	D010 D011 D012 D013 D140 D141 D142 D143
	DYNAGEN™	D020 D021 D022 D023 D150 D151D152 D153
	AUTOGEN™	D030 D031 D032 D033 D044 D045 D046 D047 D160 D161 D162 D163 D174 D175 D176 D177
	PUNCTUA™	E050 E051 E052 E053 F050 F052
	ENERGEN™	E140 E141 E142 E143 F140 F141 F142 F143
	INCEPTA™	E160 E161 E162 E163 F160 F161 F162 F163
	TELIGEN™	E102 E103 E110 E111 F102 F103 F110 F111
	RESONATE™	D420 D421 D432 D433 D520 D521 D532 D533
	PERCIVA™	D400 D401 D412 D413 D500 D501 D512 D513
	CHARISMA™	D320 D321 D332 D333
	VIGILANT™	D220 D221 D232 D233
	MOMENTUM™	D120 D121
CRT-Ds	ORIGEN™	G050 G051 G056 G058
	INOGEN™	G140 G141 G146 G148
	DYNAGEN™	G150 G151 G154 G156 G158
	AUTOGEN™	G160 G161 G164 G166 G168 G172 G173 G175 G177 G179
	ENERGEN™	N050 N051 N052 N053 P142 P143
	PUNCTUA™	N140 N141 N142 N143 P052
	INCEPTA™	N160 N161 N162 N163 N164 N165 P162 P163 P165
	COGNIS™	N106 N107 N108 N118 N119 P106 P107 P108
	RESONATE™	G424 G425 G426 G428 G437 G447 G448 G524 G525 G526 G528 G537 G547 G548
	CHARISMA™	G324 G325 G328 G337 G347 G348
	VIGILANT™	G224 G225 G237 G247 G248
	MOMENTUM™	G124 G125 G126 G128 G138
S-ICD	EMBLEM™	A209 A219