

Review, Report, Print, and Reset Clinical Event Messages

SUMMARY

Boston Scientific pulse generators provide Clinical Event messages which include important diagnostic information related to device performance and certain patient heart health information. This article describes a process to review and reset Clinical Event messages in the programmer System Summary screen. If Clinical Events are not reset, future occurrences of the same patient/device condition will not trigger the generation of an Alert (Clinical Event notification)¹ in the LATITUDE® remote monitoring system.

Products Referenced

LATITUDE® Patient Management system, COGNIS®, CONTAK RENEWAL®, LIVIAN®, TELIGEN®, VENTAK PRIZM®, VITALITY®, and CONFIENT®

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

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Boston Scientific pulse generators include system diagnostics, which are intended to assist clinicians in evaluating device and lead performance as well as certain patient heart health information. The programmer's System Summary screen in CONTAK RENEWAL® and LIVIAN® families of CRT-Ds, and VENTAK PRIZM®, VITALITY®, and CONFIENT® families of ICDs, provide a summary of certain diagnostic information in the Clinical Events message window.

Clinical Events and In-Clinic Follow-ups

Clinical Event messages are available via the programmer during in office follow-ups (typically scheduled every three months). They are displayed for informational purposes as well as when the device has detected a condition that may prompt physician action. For example, a Clinical Event message such as "No Episodes since <date>" is informational, whereas a Clinical Event message such as "Daily measurement is out of range" is intended to prompt the physician to further investigate the clinical significance and potential effect on patient therapy. At each routine in-clinic follow-up, the health care practitioner should review the System Summary screen. In addition, the clinician may review, report, print and reset (refer to Table 1) Clinical Event messages which are displayed in the Clinical Event window of the System Summary screen.

Clinical Events and LATITUDE® Patient Management Alerts

If remote monitoring is used, the physician will be notified of a Clinical Event (generated within the implanted device) via an Alert from LATITUDE¹. LATITUDE will send one Alert notification the first time the patient/device condition occurs. Notification for a new occurrence of the same patient/device condition will not be sent until the Clinical Event is reset at an in-clinic programmer follow-up. Completing the process to reset Clinical Events via the programmer allows LATITUDE to generate new Alert notifications in the event that the patient/device condition recurs.

NOTES:

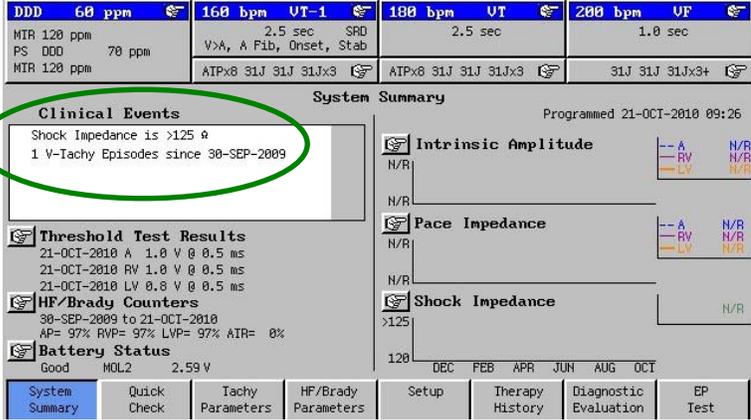
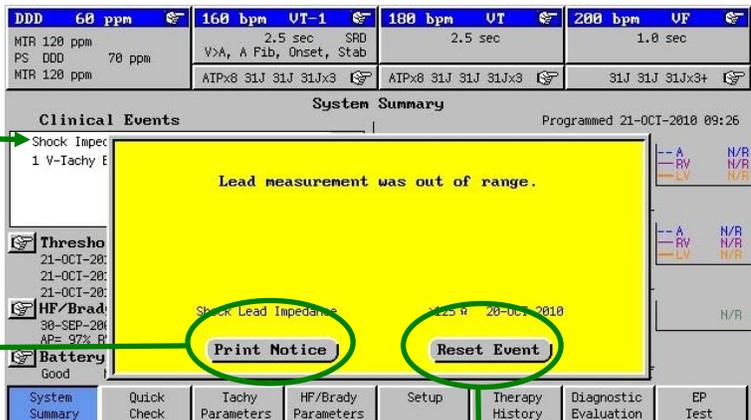
- *Not all Clinical Event messages can be reset. For example, 'Battery at ERI', 'Battery at EOL', and 'Tachy Mode = <mode>' (displays something other than Monitor + Therapy) are Clinical Event messages that do not require reset or cannot be reset.*
- *This article does not apply to COGNIS® and TELIGEN® devices. For those devices, Clinical Events are either automatically reset upon device interrogation with a programmer, or the user is prompted to print and clear any Clinical Events or Fault Messages upon device interrogation with a programmer.*

¹Clinical Event notifications (Alerts) within the LATITUDE Patient Management system are designed to notify the physician of potential health or device problems. Depending on configuration, alert conditions can be detected as often as daily or weekly, allowing changes in patient/device condition to be recognized and action to be taken as necessary. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Process to Review, Report, Print, and Reset Clinical Events in the programmer System Summary Screen

Table 1 describes a process to review, report, print and reset Clinical Events in the System Summary screen for LIVIAN and CONTAK RENEWAL families of CRT-Ds, and CONFIENT, VENTAK PRIZM, and VITALITY families of ICDs.

Table 1. How to reset Clinical Events in the System Summary screen.

Action	Instruction
Review	<p>Review and if necessary, investigate and act upon the Clinical Event.</p> 
Report	<p>As appropriate, report the Clinical Event (e.g., inform your local Boston Scientific representative or call Technical Services).</p>
Print	<p>To print the Clinical Events:</p> <ol style="list-style-type: none"> Tap anywhere on the message text within the white Clinical Events window on the System Summary programmer screen; a yellow message window appears. Select the Print Notice button. 
Reset	<p>To reset the clinical events:</p> <ol style="list-style-type: none"> Select the Reset Event button in the yellow message box. The message box automatically disappears. <p>NOTE: <i>Print before resetting, as the option to print is no longer available once the Reset Event button is selected.</i></p> Resume normal testing. <p>NOTE: <i>The Clinical Event has been reset.</i></p> 