

Investigate, Report, Print and Reset Clinical Event Messages in the System Summary Screen

BACKGROUND INFORMATION

Clinical Events, as displayed within the programmer System Summary screen for ICDs and CRT-Ds, provide clinicians with actionable and clinically relevant diagnostic information. This article (first published as a *Product Update* on May 1, 2006) describes four simple steps (investigate, report, print, reset) to be considered upon viewing a Clinical Event message. Performing these steps ensures Clinical Events that have already been investigated are reset, and will be properly identified in the event that the device/patient condition recurs.

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

Clinical Event notification (Alert): With the LATITUDE system, health care practitioners can remotely monitor specific patient and device functions by utilizing Clinical Event notifications. By enabling this level of monitoring, daily/weekly review of device function and patient condition allows changes to be recognized early and clinical action to be taken as needed.

CRM PRODUCTS REFERENCED*

ICDs, CRT-Ds,
LATITUDE Patient Management

*Products referenced herein may not be approved in all geographies.

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Boston Scientific implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) include several diagnostic tools intended to assist clinicians in evaluating device performance as well as the patient's condition. When the patient is in the clinic, the programmer's System Summary screen provides diagnostic information regarding the patient and ICD/CRT-D system, including a Clinical Events section. This section displays important messages notifying clinicians of conditions that may warrant further investigation.

Clinical Events: Investigate, Report, Print and Reset

Messages are displayed within the Clinical Events section of the System Summary screen for informational purposes as well as when the device has detected a condition that may prompt physician action. For example, an informational Clinical Event message such as "No Episodes since 14-MAR-2006" requires no further action, while a Clinical Event message such as "Daily measurement is out of range" is intended to prompt the physician to further investigate the clinical significance of the message and evaluate the potential effect on patient therapy. At each in-clinic evaluation, it is important for the health care practitioner to consider the following: investigate, report, print and reset all Clinical Events in the System Summary screen. Table 1 lists Clinical Events that can/cannot be reset.

Table 1. Clinical Events that can and cannot be reset

Examples of Clinical Events that can be reset:	Examples of Clinical Events that <u>cannot</u> be reset:
<ul style="list-style-type: none"> ▪ Shock Impedance is <20Ω, >125Ω ▪ Daily Measurement is out of desired range ▪ Patient Triggered Monitor (i.e. if feature programmed ON then patient can trigger data storage with magnet application during symptomatic episode) ▪ Number of V-Tachy episodes since given date 	<ul style="list-style-type: none"> ▪ Battery at ERI (Elective Replacement Indicator) ▪ Battery at EOL (End of Life) ▪ Tachy Mode displays programmed mode other than 'Monitor + Therapy' ▪ No Episodes since given date ▪ No V-Tachy Episodes since given date

How Clinical Events Relate to LATITUDE

As stated above, Clinical Event messages are available via the programmer during in-office visits (typically scheduled every three months). With the LATITUDE Patient Management System, Clinical Event notifications (Alerts) can be sent to a physician daily or weekly while the patient is away from the clinic.¹ One Clinical Event notification is sent the first time the patient/device condition occurs. However, after the Clinical Event message is investigated and reset during an in-clinic programmer session, LATITUDE will send a new notification if the patient/device condition recurs. If the Clinical Event is not reset, no additional notifications will be sent for that specific patient/device condition. Table 2 provides instruction on how to reset Clinical Events.

¹Clinical Event notifications are sent if the following conditions are met: enrolled physician and patient, utilizing remote monitoring, with Clinical Event notifications "ON."

Table 2. Steps to Consider when Resetting Clinical Events in the System Summary Screen

Step	Action	Instruction
1	Investigate	Read and if necessary, investigate, troubleshoot and address the Clinical Event.
2	Report	As appropriate, report the Clinical Event (e.g. inform your local representative or call Technical Services).
3	Print	<p>To print the Clinical Events:</p> <ol style="list-style-type: none"> 1. Tap anywhere on the message text within the white Clinical Events window on the System Summary programmer screen; a yellow message window appears (Figure 1). 2. Select the Print Notice button.
4	Reset	<p>To reset the clinical events:</p> <ol style="list-style-type: none"> 1. Select the Reset Event button in the yellow message box. The message box automatically disappears (Figure 1). Note, <u>print before resetting</u>, as the option to print is no longer available once the Reset Event button is selected. 2. Resume normal testing (note, the Clinical Events have been reset, Figure 2).

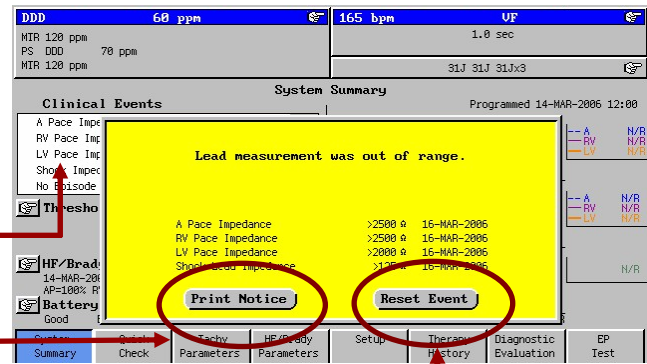


Figure 1

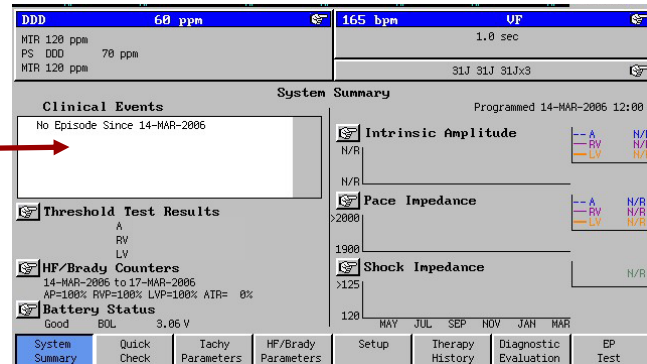


Figure 2