

Disabling of Real-time Diagnostics and Telemetry in Boston Scientific Defibrillators Due to Programmer Inactivity

SUMMARY

In order to preserve battery longevity, Boston Scientific CRT-Ds and ICDs disable real-time diagnostic functions (electrocardiograms and event markers) when there has been no telemetry communication between the implanted device and programmer for a specified period of time. This article describes these scenarios.

CRM Products Referenced

The following device families are trademarks of Cardiac Pacemakers Inc., a Boston Scientific company: COGNIS, CONFIENT, LATITUDE, LIVIAN, VENTAK PRIZM, PRIZM 2, TELIGEN, VITALITY, VITALITY 2, CONTAK RENEWAL, RENEWAL 2, 3 and 4, ZIP, and ZOOM. Products referenced herein 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

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Boston Scientific implantable defibrillators utilize the ZOOM LATITUDE Programmer Recorder Monitor (PRM) to allow the operator to review and change parameter values, evaluate therapy history data, and assess the results of diagnostic testing. Devices with radio frequency (RF) technology (including CONTAK RENEWAL RF, CONFIENT, LIVIAN, COGNIS and TELIGEN) can communicate with the PRM without a wand following the initial interaction (handshake) between the device and the PRM. This wandless/wireless, two-way RF communication technology eliminates the need to position the wand in close proximity to the device and is referred to as ZIP Wandless Telemetry. Both wanded and wireless telemetry are subject to certain time constraints.

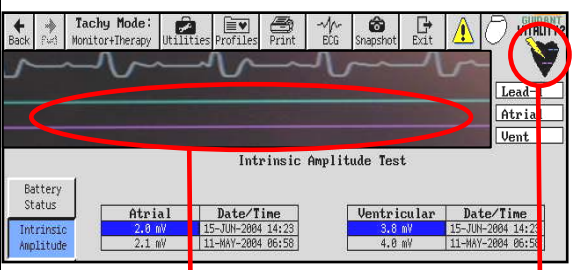
Disabling of Telemetry and Diagnostic Tools

During a telemetry session, if the device and programmer do not interact (touchscreen selections, printing, PRM-to-PG communication, disk activity) for an extended period of time, telemetry and diagnostic tools (real-time electrograms [EGMs] and event markers) are automatically disabled to preserve device battery life. The duration necessary to initiate this condition ranges between 2 and 73 minutes depending on device model, length of time since implant, and type of telemetry (wanded or wireless).

Inductive (wanded) Telemetry

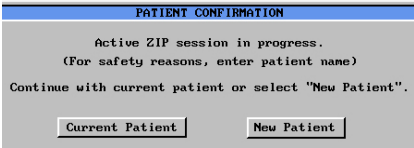
During an inductive telemetry session, if the wand is out of range of the device for 60 minutes, telemetry and all active real-time diagnostics will be disabled. When this occurs, the programmer screen will display “- -” in the heart rate icon (rather than a heart rate) and the real-time EGM will be flat with no visible markers (Table 1).

Table 1. Disabling of Telemetry/Real-Time Diagnostics—Inductive Telemetry

| Duration of wand removal | Programmer status screen | Device status and further instructions |
|--------------------------|--|--|
| After 60 minutes: |  | <p>Real-time diagnostic tools are disabled</p> <ul style="list-style-type: none"> ➤ Change any of the intracardiac EGM channels. <p>(e.g., from the Shock channel, select “Vent” and then change back to “Shock”.</p> |

RF (wireless) Telemetry

During an RF telemetry session, if no device-PRM interaction occurs for a specific period of time, the patient confirmation window will be displayed (Table 2). In COGNIS and TELIGEN devices, a series of status screens will be displayed at predetermined times (Table 3).

| Table 2. Disabling of Telemetry/Real-Time Diagnostics—RF Telemetry (RENEWAL, CONFIENT, and LIVIAN) | | |
|---|---|--|
| Duration of programmer inactivity | Programmer status screen | Device status and further instructions |
| <p>After 2 minutes:</p> <p>Patient Confirmation window is displayed.</p> <p>NOTE: The time until the display of this window is extended to 15 minutes if the device was in Storage Mode at the beginning of the programming session.</p> |  | <p>Real-time EGMs and markers continue, and the Patient Confirmation window is displayed on the programmer to confirm interest in continuing the session.</p> <ul style="list-style-type: none"> ➤ Select Confirm to continue with the session. ➤ Select End Session to end all telemetry and real-time diagnostics. |


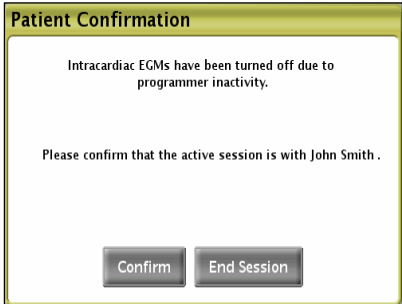
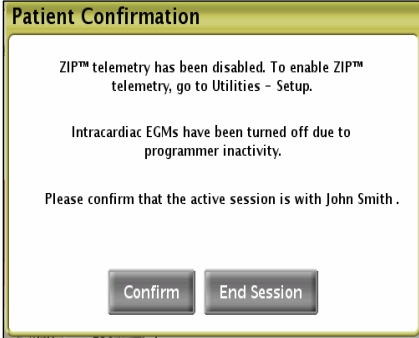

| Table 3. Disabling of Telemetry/Real-Time Diagnostics—RF Telemetry (TELIGEN and COGNIS) | | |
|---|--|--|
| Duration of programmer inactivity | Status screen on programmer | Device status and further instructions |
| <p>After 2 minutes:</p> <p>NOTE: The time until the display of this window is extended to 15 minutes if the device was in Storage Mode at the beginning of the programming session.</p> |  | <p>Real-time EGMs and markers continue, and the Patient Confirmation window is displayed on the programmer to confirm interest in continuing the session.</p> <ul style="list-style-type: none"> ➤ Select Confirm to continue with the session. ➤ Select End Session to end all telemetry and real-time diagnostics. |
| <p>After 15 minutes:</p> <p>NOTE: The time until the display of this window is extended to 28 minutes if the device was in Storage Mode at the beginning of the programming session.</p> |  | <p>Real-time EGMs and event markers are disabled to preserve battery life, and the Patient Confirmation window is displayed on the programmer.</p> <ul style="list-style-type: none"> ➤ Select Confirm to restore real-time diagnostics and continue the session. ➤ Select End Session to end all telemetry. |

Table 3. Disabling of Telemetry/Real-Time Diagnostics—RF Telemetry (TELIGEN and COGNIS), continued

| Duration of programmer inactivity | Status screen on programmer | Device status and further instructions |
|--|--|--|
| <p>After 60 minutes:</p> <p>NOTE: <i>The time until the display of this window is extended to 73 minutes if the device was in Storage Mode at the beginning of the programming session.</i></p> |  <p>Patient Confirmation</p> <p>ZIP™ telemetry has been disabled. To enable ZIP™ telemetry, go to Utilities - Setup.</p> <p>Intracardiac EGMs have been turned off due to programmer inactivity.</p> <p>Please confirm that the active session is with John Smith.</p> <p>Confirm End Session</p>  <p>Communication Reset</p> <p>A long telemetry break has ended the communication session.</p> <p>Close</p> | <p>ZIP Wandless Telemetry and real-time EGMs are disabled to preserve battery life, and the Patient Confirmation window is displayed on the programmer.</p> <ul style="list-style-type: none"> ➤ Select End Session to end all telemetry. ➤ Ensure the wand is placed over the device and select Confirm to continue the session using wandless telemetry. ➤ After selecting Confirm, to re-establish wandless telemetry, go to UTILITIES > Setup and Select Enable use of ZIP telemetry. <p>NOTE: <i>If Confirm is selected and the Communication Reset window is displayed, a new session is required to further interrogate the device. Any proposed programming changes that were not permanently programmed during the session will be lost.</i></p> |

Please review product instructions for use for information on establishing and maintaining optimal wandless communication. A Closer Look article entitled "ZIP Wandless Telemetry and the ZOOM LATITUDE Programmer" has also been prepared to summarize techniques that can be utilized to optimize ZIP wandless telemetry.