

Programming Considerations When an LV Lead Is Not Used

BACKGROUND INFORMATION

Cardiac resynchronization therapy pacemakers (CRT-Ps) and defibrillators (CRT-Ds) are intended to utilize a left-ventricular (LV) lead to re-establish synchrony between the right and left ventricles. However, there may be clinical situations in which the LV lead is not used.

For example:

- If the LV lead is unable to be positioned, the physician may temporarily elect to use the CRT device without an LV lead, plugging the unused LV header port.
- If the implanted LV lead dislodges to a sub-optimal position, the physician may leave the lead implanted and connected to the LV header port, yet elect not to use it.

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CRM PRODUCTS REFERENCED*
CONTAK RENEWAL CRT-D and CRT families

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

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The device cannot discern the presence or absence of an LV lead; therefore, if the LV lead port is plugged or if an implanted LV lead is not being used, consider reprogramming certain device parameters to avoid the following potential observations:

Diaphragmatic stimulation

If an implanted LV lead is not being used and is situated near the phrenic nerve, then it is possible for the patient to feel diaphragmatic stimulation in the following situations:

- *Daily Measurements (RENEWAL TR, RENEWAL TR 2, RENEWAL 3, RENEWAL 3 HE, RENEWAL 4 and RENEWAL 4 HE)* – When LV Lead Daily Measurements are programmed On, the device performs daily LV measurements. Because the temporary pacing output used to perform these measurements is 5.0 V or higher, the patient may feel stimulation.
- *ATR Fallback Mode* – When the device reverts to ATR Fallback Mode, it paces bi-ventricular. If LV Amplitude is not minimized, the patient may feel stimulation during ATR Fallback pacing.
- *Quick Check follow-up* – When performing a Quick Check, the LV Pace Impedance test is automatically conducted at 5.0V or higher; therefore, the patient may temporarily feel stimulation.

► If diaphragmatic stimulation is of concern, turn Off LV Daily Measurements, program the LV Amplitude/Pulse Width to the minimum value and consider performing individual commanded tests via Diagnostic Evaluation rather than Quick Check.

Erroneous LV lead diagnostic values

For RENEWAL TR, RENEWAL TR 2, RENEWAL 3, RENEWAL 3 HE, RENEWAL 4 and RENEWAL 4 HE - As long as LV Daily Measurements are programmed On, the device performs LV measurements. If the LV port is plugged and LV Daily Measurements are not programmed Off the user will observe erroneous values (i.e. >3000 Ω) displayed on the Daily Measurements screen.

► To avoid erroneous LV lead diagnostic values, simply program LV Daily Measurements Off.

Unneeded accrual of LV Counters

The number of paced and sensed LV events is displayed on the Counters screen. These events include Tracked, Device Determined, Bi-V Triggered and PVCs. LV counters are often used for the purposes of troubleshooting. When an LV lead is not in use, the device still increments the LV counters; however, they become a less valuable tool for troubleshooting. Note that the user may still observe a small percentage of LV events as the device paces bi-V during ATR Fallback.

- ▶ If the accrual of LV counters is bothersome, they can be minimized. To minimize the counters, program LV Daily Measurements to Off, program the Pacing Chamber to RV and program Bi-V Trigger to Off.

Presence of unneeded LV electrograms, markers and intervals

The LV Electrode Configuration is programmed in accordance with the number of electrodes on the LV lead. Real-time LV electrograms, markers and intervals are not available without an LV lead. Therefore, if an LV lead is implanted and not being used and the LV Electrode Configuration is appropriately programmed to Single or Dual, the device will continue to display real-time LV electrograms (if selected), markers and intervals. Note: even if real-time LV electrograms are not selected, the strips will still show LV markers and intervals.

- ▶ Currently, real-time LV electrograms, markers and intervals cannot be disabled in a Single or Dual Electrode Configuration. However, if there is no LV lead implanted, programming the LV Electrode Configuration to None will disable LV electrograms, markers and intervals.

Shortened device longevity

If an LV lead is connected to the device but is not being used and the pacing chamber and output are programmed to nominal settings, then device longevity could be shortened.

- ▶ Program the pacing chamber to RV and minimize the LV Amplitude/Pulse Width.

<p>Programming considerations a user can take to avoid the above-referenced observations can be found in the table on the following page.</p>
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**CONTAK RENEWAL CRT-Ps and CRT-Ds:
Programming Considerations When an LV Lead Is Not Used**

<p>Program appropriate HF/Brady parameters</p>	<p><u>Select HF/Brady Parameters</u></p> <ul style="list-style-type: none"> • Program Pacing Chamber to RV • Program LV Amplitude and Pulse Width to its minimum value or Off (for <u>both</u> Normal and Post-Shock Brady) <p><u>Select Tachy Response</u> (for dual-chamber modes) or <u>Rate Enhancement</u> (for single-chamber modes)</p> <ul style="list-style-type: none"> • Program Bi-V Trigger to Off <p><i>Note: Bi-V Trigger is not available in RENEWAL, RENEWAL TR, RENEWAL 3 and RENEWAL 3 HE</i></p> <p><u>Select Lead Configuration</u> (only if no LV lead is implanted)</p> <ul style="list-style-type: none"> • Program the Left Ventricle Electrode Config to None
<p>Program appropriate Daily Measurements</p>	<p><u>Select Setup / Daily Measurements</u></p> <ul style="list-style-type: none"> • Program LV Intrinsic Amplitude and LV Pace Impedance to Off <p><i>Note: Daily Measurements is not available in RENEWAL and RENEWAL 2</i></p>
<p>Follow-up via Diagnostic Evaluation</p>	<p>If performing commanded tests via Diagnostic Evaluation, perform A/RV/shock tests only.</p> <p><i>Note: If the A/RV/LV Lead Impedance button is selected and performed, it is possible the patient may feel temporary stimulation during the test, as the LV Lead Impedance test is conducted at 5.0V or higher.</i></p>
<p>Follow-up via Quick Check</p>	<p>If performing Quick Check follow-up, de-select the LV Threshold Test.</p> <p><i>Note: The LV Pace Impedance test is automatically performed during Quick Check; therefore, it is possible the patient may feel temporary stimulation, as the test is conducted at 5.0V or higher.</i></p>

Programming as listed above will help to achieve the following results:

- *Eliminate* the potential for diaphragmatic stimulation caused by an LV lead sitting near the phrenic nerve
- *Prevent* the device from reporting erroneous LV lead diagnostic values when there is no LV lead implanted
- *Minimize* the accrual of unneeded LV counters
- *Improve* device longevity of a device with an LV lead implanted but not being used