

Compilation of Device Programming and Alerting Considerations for Monitoring and Managing Leads

I. Programming Considerations

- **To clearly identify a patient with a Riata® or Riata ST Silicone Lead:**
 - Add Riata Lead descriptor to patient profile 'Notes' box
- **To use SecureSense™ RV lead noise discrimination* to monitor for noise:**
 - Set the discriminator to **On** (nominal) in order to detect and inhibit therapy for lead noise
 - Set the discriminator to **Passive** to only monitor and detect lead noise but not inhibit therapy
- **To use an EGM channel to monitor for HV lead noise:**
 - Set an unused EGM channel to '**RV Coil to SVC**' under Stored EGM Configuration settings
- **To program upper and lower limits for Pacing Lead Impedance (PLI) and High Voltage Lead Impedance (HVLI):**
 - Set the PLI 'Upper Limit' to 1000 Ohms and 'Lower Limit' to 200 Ohms
 - Set the HVLI 'Upper Limit' and 'Lower Limit' to 25 Ohms above and below the settled impedance trend rate
- **To ensure episode triggers for EGM storage, as available per device type:**
 - Verify priority is set to 'Low' for **Atrial AMS/AT/AF** episodes
 - Verify priority is set to 'High' for **VT** and **VF** episodes
 - Verify priority is set to 'Low' or 'High' for **Non-sustained VT/VF** episodes*
 - Verify priority is set to 'Low' or 'High' for **Non-sustained V Lead Noise** episodes*
 - Verify priority is set to 'Low' for **Noise Reversion** episodes.
(Note: Stores EGM but does not trigger device transmission to Merlin.net® PCN)
- **To enable appropriate patient notifications, program these vibratory patient alert triggers:**
 - RV Lead Impedance Out of Range
 - Therapy is inhibited due to Lead Noise
 - Episodes of Non-sustained Lead Noise are Detected
 - HV Lead Impedance Out of Range
 - Possible HV Circuit Damage
- **To monitor pacing thresholds:**
 - Turn RV AutoCapture™ pacing to On or RVCap® Confirm to On or Monitor, if available and as appropriate for individual DR and CRT-D patients
- **To help avoid tachy episode detection of potentially brief lead noise episodes:**
 - Change Detection Criteria for the number of VF Detection Intervals to 24 or 30 intervals

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II. Specific Considerations at Generator Replacement

- Examine portions of the lead(s) in the pocket for visual signs of insulation damage.
- A “test” high voltage shock can be delivered to ensure successful detection/ delivery of therapy.
- Select a replacement device that has an automatic vector switching capability (e.g., DynamicTx™ over current detection algorithm is designed to automatically change the programmed HV vector to enable delivery of a HV shock in the presence of a short circuit**).
 - If such a device is not available in your geography, consider reprogramming shocking vector for 8F Riata silicone leads at device replacement (e.g., use the RV coil to Can vector by turning the SVC coil “off”). When changing shocking vectors, including turning off the SVC coil, when clinically appropriate consider performing defibrillation threshold testing to ensure therapy efficacy.

III. Patient Diagnostic Reports Inspection

- **Stored EGMs / Rhythm Episodes:**
 - Check presenting rhythms / stored EGMs for noise or artifact deviations on far field sensing vectors that include RV Coil, SVC Coil, and RV Ring to compare with near field sensing
- **Ventricular Heart Rate Histogram:**
 - Check histogram for counts in the high rate bins faster than 250ms (>240 bpm) that are likely non-physiologic
- **Ventricular Lead Impedance (PLI) Trend Report:**
 - Check pacing lead impedance for variations and changes in trend since last follow-up
- **HV Lead Impedance (HVLI) Trend Report:**
 - Check high voltage lead impedance on all vectors for variation of >25% since last follow-up
 - For Atlas and Epic family devices which do not have automatic HVLI measurements, the HV lead impedance test can be performed manually through the programmer screen. Be aware that some patients may notice discomfort during the 10V stimuli required to measure the impedance.
- **Ventricular Amplitude Trend Report:**
 - Check trend for signs of decreasing amplitude or fluctuations in trend
- **RV AutoCapture™ Pacing Trend Report / RV Cap® Confirm Trend Report:**
 - Check trend for increases in pacing threshold / changes over time, if RV AutoCapture Pacing or RV Cap Confirm feature is available and enabled
- **Non-sustained VT/VF episodes and diagnostics:**
 - Check episodes and diagnostics for the number of non-sustained episodes detected and any associated stored EGMs to examine for lead noise that may have been responsible for these episodes

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- **SecureSense RV Lead Noise Detected and Non-Sustained Lead Noise Detected episodes and diagnostics:**
 - Check '*VT/VF Episodes*' for RV Lead Noise detected EGM episodes and diagnostics, and examine for lead noise that may have been responsible for these episodes
 - Check '*Other Episodes*' for Non-sustained RV Lead Noise EGM episodes detected, and examine for short bursts of lead noise that may have been responsible for these episodes

IV. Merlin.net[®] Remote Patient Monitoring

- **To ensure that patients are identified as having a Riata or Riata ST Silicone lead for ease of lead surveillance via remote monitoring:**
 - Add Riata lead descriptor to patient profile / record.
- **To ensure that remote monitoring alerts are received, possibly related to the presence of lead noise, program the following DirectAlerts[®] notifications:**
 - Set the following Alert Types to '*Urgent*' or '*Standard*', as available per device type
 - RV Pacing Lead Impedance Out of Range
 - High Voltage Lead Impedance Out of Range
 - Possible High Voltage Lead Issue
 - Sustained RV Lead Noise Detected
 - Non-sustained RV Lead Noise Detected
 - Ventricular Noise Reversion
- **To ensure that the clinic receives the alerts on Merlin.net PCN:**
 - Patients need to have their Merlin@home[®] transmitters connected via landline, cellular adapter or broadband connectivity to receive software updates that will enable the new alert types on Merlin.net PCN and transmit these alerts to Merlin.net PCN.
- **To ensure that appropriate clinic personal receive remote monitoring alerts which could be related to the presence of lead noise:**
 - Revise 'Clinic Preferences' for DirectAlerts[®] distribution, as appropriate

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Merlin.net[®] PCN – Patient Diagnostic Reports Inspection

Review the **Recent Transmissions** screen on Merlin.net PCN for the list of patients with alert conditions and associated device report transmissions

What to look for to monitor implanted lead integrity -

- **Merlin.Net PCN ‘Alert Summary’ report**
 - Check list of device triggered alerts and or remote monitoring alerts for episodes pertaining to potential RV lead related issues
- **Stored EGM episode reports**
 - Check EGMS for the presence of lead noise on each of the available channels, especially episodes identified as **VT/VF**, episodes identified as **Non-sustained VT/VF**, and **Sustained RV Lead Noise Detected** and **Non-Sustained RV Lead Noise Detected** episodes.
- **‘Ventricular Heart Rate Histogram’ report display**
 - Check histogram for counts in the high rate bins faster than 250ms (>240 bpm)
- **‘Ventricular Lead Monitoring’ Impedance (PLI) Trend report display**
 - Check for impedance changes from baseline trend
- **‘HV Lead Monitoring’ Impedance (HVLI) Trend report display**
 - Check for impedance changes from baseline for all 3 vectors
- **‘Ventricular Amplitude’ trend report display**
 - Check for changes in pacing amplitude and trends
- **RV AutoCapture™ Pacing Trend / RV Cap[®] Confirm Trend report display, if available and enabled**
 - Check for increases in pacing threshold and changes over time

Note: Every case is unique; therefore physicians should decide the best treatment option for their patient

If you have any questions or concerns about available device features or programming options, please do not hesitate to contact St. Jude Medical Technical Services (1-800-PACEICD) or your local St. Jude Medical representative.