REMOTE CARE ALERT MANAGEMENT REFERENCE GUIDE
Managing Merlin.net® Patient Care Network (PCN) Alerts

Merlin.net PCN offers a powerful range of alert capabilities to give your practice the control, flexibility and capabilities you need to manage your patients. This educational guide provides an overview of how you can make the most of the St. Jude Medical remote monitoring capabilities by:

- Describing the multiple types of alerts
- Showing how to clear alert conditions
- Indicating which alerts are available in different types of devices

MERLIN.NET PCN ALERT MANAGEMENT BASICS
Successful alert management with Merlin.net PCN begins on the Clinic Administration Screen.

- On the Recent Transmissions screen, go to the Clinic Administration tab and select the DirectAlerts™ Settings options from the menu.
  - Clinic-level preferences based on device type can be made here.
  - Think of your selections as standing orders that are applicable to the majority of your patients.
- All ICD/CRT-D (tachycardia) Merlin.net PCN alerts can be found under the ICD/CRT-D menu.
- All pacemaker (bradycardia) Merlin.net PCN alerts can be found under the Pacemaker/CRT-P menu.
- Changes to clinic-level (Clinic Administration) alert selections will update all patient-level (within the patient profiles) alert selections, except those in Override.
  - Override indicates a selection within a patient’s profile that differs from the clinic preferences.
ALERT PRIORITY LEVELS

Any selected Merlin.net PCN alert can trigger a transmission during the daily DirectAlerts™ notification check. Priority levels (Red or Yellow) affect:

- When and how clinics or clinicians are notified of alerts.
- How transmissions are categorized on the Recent Transmissions list.

If your clinic has decided against sending alert notifications to the clinic or clinicians, select the Off option.

If the Off option is selected for an alert, the Merlin@home™ transmitter will not look for this alert during the daily device check, and therefore, will not initiate a transmission based on the presence of this alert. However, if this alert has occurred, a scheduled transmission or a patient-initiated transmission will display the alert on the Alert Summary report.

All transmissions with or without alerts will appear on the Recent Transmission screen. If the clinic or clinicians want to be notified of alerts, then prioritization may be used.

ALERT DISTRIBUTION AND NOTIFICATION

The option for clinic or clinician notification can be found on the DirectAlerts Notification Alerts and Medical Team settings within the ICD/CRT-D page and the Pacemaker/CRT-P pages. Merlin.net PCN alerts are highlighted on the main page of your Merlin.net PCN website. When an alert-initiated, scheduled or patient-initiated transmission is received by Merlin.net PCN, the system will categorize the transmission and distribute an alert notification to the clinic and a clinician, based on the highest priority alert classification of new alerts within the transmission. (Red is higher priority than yellow.)

Note: An alert is considered new if it has not been previously reported since that last time the patient’s device was interrogated by a Merlin™ programmer in the clinic.

To notify the clinic of alerts:
Select a notification method (phone, SMS text, fax or e-mail) for:

- each alert category,
- office hours and
- after-hours alert delivery.

Note: Numbers and addresses used for notification are those listed in the Clinic Profile. If you do not want alerts sent to the clinic, select the None option from the drop-down menu. This selection only affects clinic notification of the alert and has no impact to the Recent Transmissions screen.

To notify a Medical Team member of alerts after hours:
When an alert-initiated, patient-initiated or scheduled transmission is received outside of the clinic’s defined hours, an alert will be sent to a member of the patient’s medical team if the transmission contains a new Red or Yellow alert.

1. First, a few notes about a patient’s medical team:
   A patient’s medical team is defined in the patient profile. (NOTE: One or more members can be selected.)

2. All patients have a medical team member named On Call Physician.

3. The medical team order can be defined. This order defines the order in which alert distribution will be applied.

4. Each medical team member can define if they want to receive after-hours alert notifications or not.
When an after-hours transmission is received, and the system determines that an alert notification is to be sent to the medical team, the system will traverse the medical team, in order, and attempt to send the alert notification to the first member of the medical team who is set up to accept after-hours notifications. In the event that none of the named medical team members are set up to accept after-hours notifications, then the system will distribute the alerts to the On Call Physician medical team member.

- **IMPORTANT:** This is only an after-hours option; it is not valid during regular clinic hours.
- **NOTE:** If distribution to the Medical Team is enabled, the On Call Physician contact information must be defined in order to ensure that there is at least one medical team member who can receive the alert notification.
- **NOTE:** When an alert is received, the clinician listed first on the Medical Team in a Patient’s Profile will be notified immediately, which may be as early as 2 a.m.

**To send alert notifications to physicians on their smartphones or mobile devices:**

- Enter a security stamp into the security stamp field.
  - For a specific physician, this information should be entered in that specific User’s Profile.
  - For an on-call physician, this information should be entered in the Clinic Profile.
  - Security stamp rules are available via a link on the screen.
- Select e-mail for After Hours contact method.
  - The e-mail address entered must be one that is set up for smartphone or mobile device access.
- Devices must have an Internet connection and an advanced browser.
- Devices supported include:
  - iPhone™ 3G and higher
  - iPad™ tablet
  - Android™
  - Windows™ Phone 7.0 and higher

**TYPES OF MERLIN.NET PCN ALERTS**

St. Jude Medical provides a system that allows you to customize care for all of your patients. The system contains the implanted device, the Merlin™ Patient Care System (PCS), the Merlin@home transmitter and the Merlin.net Patient Care Network (PCN). The system provides flexibility and customization to allow you to optimize the management of your patients.

The three types of St Jude Medical alerts:

1. **Device Alerts:** These alerts pertain to the basic functions of the implantable system, including the device and the lead. As such, these alerts are typically always on in the device and cannot be programmed off. Clearing the alert requires taking corrective actions to ensure that the implantable system is in working condition. Device alert examples include Device Reset, Backup VVI, Lead Impedance out of range and ERI.

2. **Clinical Alerts:** These alerts indicate that the implantable system has observed a clinical condition in the patient that might be of interest to the clinician to manage their patient. By nature these alerts are patient dependent, so they are typically customizable using a Merlin PCS programmer. These alerts get cleared alongside clearing diagnostics. Clinical alerts examples include AT/AF Burden, PMT and percent pacing.

3. **Informational Alerts:** These alerts communicate information about the implantable system that might be of interest to the user. These alerts do not communicate critical issues with the implantable system, or clinical conditions about the patient. Informational alert examples include <2:1 Pacing Safety Margin, Leads Uncoded, Patient Notification was delivered and Magnet Reversion occurred.

**ALERTS CUSTOMIZATION**

Since Device Alerts are related to the basic functionality of the implantable system, they cannot be customized or turned off. In contrast, the Clinical Alerts are related to the patient’s condition and thus should be customized per patient. The customization can be done using a Merlin PCS. The default triggers for these alerts are typically set to a sensitive setting in the device to ensure that the clinician does not miss any
critical patient events. For instance, the setting to trigger an AT/AF Episode Duration is defaulted to an AT/AF that lasts 3 hours. This setting may not be appropriate for patients with persistent or paroxysmal AT/AF. The Merlin PCS programmer is used to adjust this trigger threshold.

It is particularly important to customize Clinical Alerts for patients who are monitored using Merlin.net Patient Care Network (PCN). This is because Merlin.net PCN generates a transmission whenever a Clinical Alert is detected by the implantable system. As such, inappropriate alert trigger thresholds in the implantable system can result in an inappropriate Merlin.net PCN transmission.

The alert triggers can only be customized using Merlin PCS programmer; however, whether an alert initiates a remote transmission can be adjusted on Merlin.net PCN without the need of a Merlin PCS. This customization can be done at the clinic level as well as per patient. The customization can be done at any time on the DirectAlerts Notification tab.

The alerts displayed on Merlin PCS are designed to notify the clinician about any potentially important events since the last follow-up. As such, there is a larger selection of alerts available on Merlin PCS programmer. In contrast, the purpose of Merlin.net PCN DirectAlerts notifications is to notify the clinician of any adverse events that require immediate intervention. As such, DirectAlerts notifications are a subset of alerts available on Merlin PCS. For instance, Magnet Reversion alert is available on Merlin PCS but not as a DirectAlerts notification on Merlin.net PCN. However, once a transmission is uploaded, all alerts will be displayed on the reports to ensure that the clinician gets the same information from the remote follow-up than they would from an in-clinic visit. Please note that all DirectAlerts notifications are defaulted on, so it is important to customize DirectAlerts notifications per patient in order not to receive inappropriate alert-initiated transmissions.

This process can be addressed in just two steps:

1. Discuss the alerts in the device and setting up any alert configurations in the device using the programmer.
2. Discuss monitoring/reporting alerts using Merlin.net PCN.

Remember that Merlin.net PCN does not set the alerts in the patient’s device. Rather, Merlin.net PCN only monitors and reports on alerts that are detected within the device.

**PROGRAMMER ALERTS AVAILABLE ON MERLIN.NET PCN**

Not all programmer alerts displayed on the FastPath™ Summary are selectable on Merlin.net PCN for alert notifications. Likewise, not all Merlin.net PCN alerts are displayed on the FastPath Summary. The Alert Summary is the only comprehensive list of alerts within a transmission.

Only alerts selectable in Merlin.net PCN within a patient’s profile can trigger an alert-initiated transmission.

- Select programmer alerts seen only on the FastPath Summary:
  - Note highlighted for your attention
  - Pacemaker-mediated Tachycardia (PMT)
  - Auto Mode Switch (AMS)
  - Magnet Reversion
  - Morphology Template
  - Noise Reversion
  - Patient Notifier
  - High Output State (for Ventricular AutoCapture™ pacing system or capture confirmation)

**MERLIN.NET PCN DISPLAYS—EPISODES WITH ALERT CONDITIONS**

Episodes with Alert Conditions and the number of episodes with conditions are displayed within the Alert Episodes column of the Recent Transmissions screen. The specific alert conditions are located on the “Episodes/ EGMs” tab, along with any corresponding EGMs. The alerts below are some of those that will appear on the “Episodes/EGMs” tabs when you view the actual EGMs. This list is not comprehensive.

- High-voltage lead impedance out of range
- Possible output circuit damage detected
- Noise reversion
- Charge time limit reached
- All therapies delivered without terminating arrhythmia
- At least one shock unsuccessful
- Duration > one minute
- Therapy-accelerated rhythm
- Delivered shock truncated at 12 milliseconds
- Supraventricular tachycardia (SVT) discriminators disagree
- Anti-tachycardia Pacing (ATP) therapy unsuccessful
- SVT discriminator override/SVT criteria time out (maximum time to diagnostic [MTD])
- Greater than or equal to three ventricular tachycardia/ventricular fibrillation (VT/VF) episodes in 24 hours
- Ventricular tachycardia therapy time out (maximum time to fibrillation [MTF])
- Non-sustained episode
- Magnet reversion

**EGMS**
Merlin.net PCN displays only new EGMs (old EGMs that have been viewed previously are not visible). An EGM is considered “viewed” if it has been displayed in-clinic on the programmer or sent to Merlin.net PCN as a result of a patient-initiated or scheduled transmission. Therefore, if a patient’s device initiates frequent alert-initiated transmissions, the same EGMs may be re-sent with each transmission, since Merlin.net PCN does not consider those EGMs “viewed.”

- Post-ICD implant, the following situation may occur: the Merlin@home transmitter sends an alert-initiated transmission for high-voltage therapy delivered, yet no EGM is displayed with the transmission.
- This occurs because defibrillation threshold (DFT) testing results in shock delivery that is new to the transmitter. However, because the EGM was viewed on the programmer, it is considered previously viewed and is therefore not sent.
- To avoid this situation, clear the Episode Directory after DFT testing.

- Another scenario occurs if a patient comes into the clinic after receiving a shock or ATP.
- After the visit, the Merlin@home transmitter sends an alert-initiated transmission for successful ATP or high-voltage therapy delivered for episodes the clinician has previously viewed.
- To avoid this situation, clear the Episode Directory after clinic visits.

**CLEARING ALERTS AND DATA FROM MERLIN.NET PCN**
Within the Merlin.net PCN patient profile, you have the option to clear diagnostics, episodes and/or EGMs. Any patient-initiated or scheduled remote transmission will obey the clearing settings indicated in the Merlin.net PCN patient profile. These settings will clear the selected data from the implanted device. Note: For any previously reported EGMs, episodes diagnostics are retained and can be referenced in Merlin.net PCN. Clearing is applicable to the device and will not erase information in Merlin.net PCN.

- To clear AT/AF alerts, select clear episodes in the profile.
- To clear high ventricular rate alerts, select clear episodes in the profile.
- To clear counter alerts associated with VT and VF episodes, select clear episodes directory in the profile.
- To clear EGMs, select clear EGMs in the profile.
- Alert-initiated transmissions do not clear any of the selections.
# Types of Merlin.Net Patient Care Network Alerts

<table>
<thead>
<tr>
<th>Alert Description</th>
<th>Clearing</th>
<th>Clinic Alerts</th>
<th>Device Alerts</th>
<th>Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tachycardia Therapy Disabled</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Enable the tachy therapy zones</td>
</tr>
<tr>
<td>Device Programmed to Emergency Pacing Values</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Program to normal output</td>
</tr>
<tr>
<td>Charge Time Limit Reached</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Manual Capacitor maintenance has to be performed</td>
</tr>
<tr>
<td>Possible High-Voltage Circuit Damage</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>May require DFT testing to be performed</td>
</tr>
<tr>
<td>Longevity Analysis (requires Technical Services Support)</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Additional Technical Services involvement needed</td>
</tr>
<tr>
<td>Device Reset</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Additional Technical Services involvement needed</td>
</tr>
<tr>
<td>Back-up Ventricular-inhibited (VVI) Pacing</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Additional Technical Services involvement needed</td>
</tr>
<tr>
<td>Device at Elective-Replacement Indicator (ERI)</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>Additional Technical Services involvement needed</td>
</tr>
<tr>
<td>Atrial Pacing Lead Impedance Out of Range</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>In-clinic manual valid lead impedance has to be performed</td>
</tr>
<tr>
<td>Left Ventricular Pacing Lead Impedance Out of Range</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>In-clinic manual valid lead impedance has to be performed</td>
</tr>
<tr>
<td>LeadAssurance™ Alert: RV Pacing Lead Impedance Out of Range</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td>In-clinic manual valid lead impedance has to be performed</td>
</tr>
<tr>
<td>LeadAssurance™ Alert: High-Voltage Impedance Out of Range</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LeadAssurance™ Alert: Possible High-Voltage Lead Issue</td>
<td>In-Clinic</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LeadAssurance™ Alert: Sustained RV Lead Noise Detected</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LeadAssurance™ Alert: Non-sustained RV Lead Noise Detected</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LeadAssurance™ Alert: V. Noise Reversion</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VT/VF Episode Occurred</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-sustained VT Episode Occurred</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-sustained VF Episode Occurred</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT/AF Episode Duration &gt; Threshold</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT/AF Burden &gt; Threshold</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Ventricular Rate During AT/AF &gt; Threshold</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High-Voltage Therapy Delivered</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Successful Anti-Tachycardia Pacing (ATP) Delivered</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapy Accelerated Rhythm</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Ventricular Pacing Greater Than Limit</td>
<td>Clear Diagnostics</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bi-Ventricular Pacing Less Than Limit</td>
<td>Clear Diagnostics</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three or More VT/VF episodes in 24 hours</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At Least One Shock Unsuccessful</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Therapies Exhausted</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Ventricular Rate Episodes Recorded</td>
<td>Clear Episodes</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MANAGING AT/AF ALERTS ON MERLIN.NET PCN

Thresholds and Burdens for AT/AF alerts are programmed in the device. Therefore, Merlin.net PCN will detect if an alert condition is present based on the programmed device parameters.

- For Merlin.net PCN to receive AT/AF Alerts, the alert must be selected for monitoring within the device. The alert must be programmed in the device and in the patient profile in Merlin.net PCN.

- AT/AF alerts may not always send an associated EGM, even though a transmission is sent. The type of EGMs collected by the device is dependent on the selected atrial episode chosen for storage by the programmer (options include AMS entry, AMS exit, AMS entry and exit, AT/AF detection or high atrial rate). Note: Storage options are device dependent.

- If frequent AT/AF alert-initiated transmissions are being sent, the clinic has some options. Based on the patient’s medical management and physician preferences, the programmed parameters of the AT/AF alerts may be optimized in the device using the Merlin PCS programmer. Alternatively, AT/AF alerts may be turned off of the patient profile by setting the alert to Off. This will prevent the Merlin@home transmitter from generating a transmission due to an AT/AF alert.

- If an AT/AF alert is turned off in the patient profile in Merlin.net PCN, but remains on in the device, patient-initiated or scheduled transmissions will display the alert condition in the Alert Summary only, and no alert notification will be sent.

A check box in the Show on FastPath Summary box means that Merlin.net PCN will monitor the alert condition.
Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

iPhone and iPad are trademarks of Apple Inc. Android is a trademark of Google Inc. Windows is a trademark of Microsoft.

Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies. © 2014 St. Jude Medical, Inc. All Rights Reserved.

SJM-MER-0914-0022 | This document is approved for global use.