Tech Corner

Alerts - System, Lead, Tachy Therapy and Clinical Alerts

NOTE: PLEASE NOTE THAT THE FOLLOWING INFORMATION IS A GENERAL DESCRIPTION OF THE FUNCTION. DETAILS AND PARTICULAR CASES ARE NOT DESCRIBED IN THE ARTICLE. FOR ADDITIONAL EXPLANATION PLEASE CONTACT YOUR SALES REPRESENTATIVE.

NOT AVAILABLE FOR DISTRIBUTION OR SALE IN THE USA.

MicroPort™ CRM

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Alerts

System, Lead, Tachy Therapy and Clinical Alerts

AVAILABILITY

The alerts described in this article are available in the MicroPort ICDs and CRT-Ds devices providing the RF feature. Refer to the user's manual furnished with the device for complete instructions for use (www.microportmanuals.com).

INTRODUCTION

In patients' daily life, some clinical or device-related events need to be communicated to the physician or someone in the hospital or clinic's team.

In a generic way:

- **Device-related** situations that are potentially dangerous are detected and communicated by the implanted device to the SMARTVIEW system through the remote monitor: these are labeled as: CRITICAL.
- **Clinical** situations that are potentially dangerous are detected and communicated by the implanted device to the SMARTVIEW system through the remote monitor: these are labeled as: SIGNIFICANT.

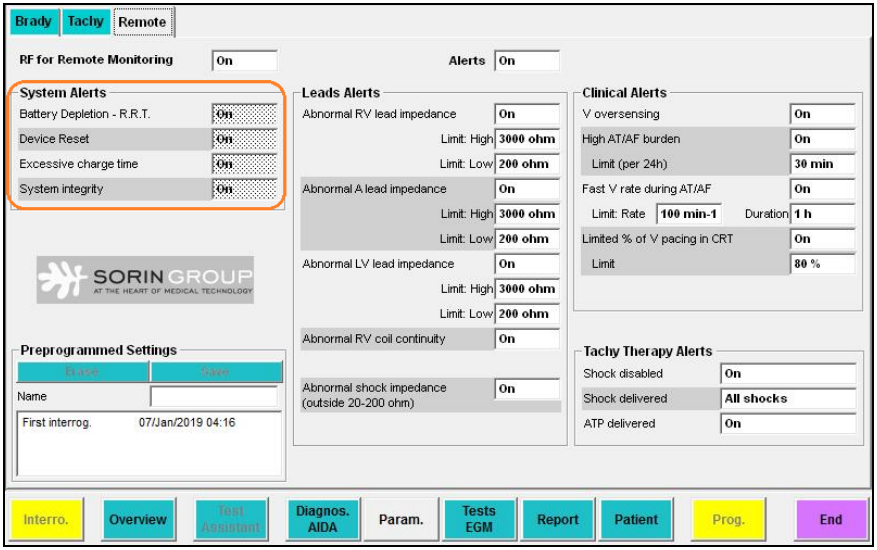
Alerts are ALWAYS programmed through the programmer. They are triggered automatically by the device when the selected event occurs. Every night, at a time between midnight and 5:00am*, the remote monitor checks the device for any new alert.

Alerts can be:

- System Alerts
- Lead Alerts
- Tachy Therapy Alerts
- Clinical Alerts

* *Programmable from the website*

SYSTEM ALERTS



Battery

Battery depletion – RRT (Recommended Replacement Time)

- Available in VR, DR and CRT-D
- Critical alert CRITICAL
- Non programmable: always ON
- The battery voltage is measured every day
- The alert is triggered when the RRT (2.62 V) has been reached for 5 consecutive days and/or the measured battery voltage is less than 2.6 V

Excessive consumption

- Available in VR, DR and CRT-D
- Highly critical alert CRITICAL
- Non programmable: always ON
- The alert is triggered if the device detects high consumption measurements

Device reset

- Available in VR, DR and CRT-D
- Highly critical alert CRITICAL
- Non programmable: always ON
- The alert is triggered after a software/hardware or memory issue

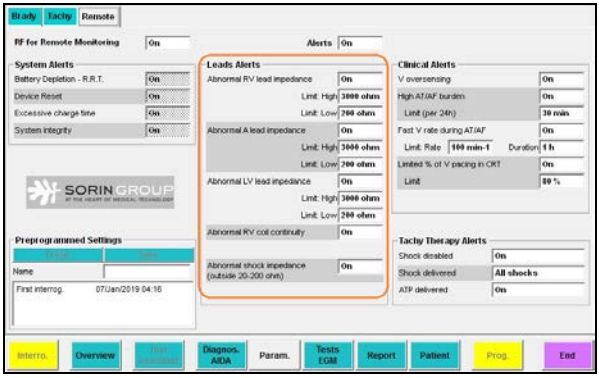
Excessive charge time

- Available in VR, DR and CRT-D
- Highly critical alert CRITICAL
- Non programmable: always ON
- The alert is triggered when the charge time is longer than 25 seconds

System integrity

- Available in VR, DR and CRT-D
- Highly critical alert CRITICAL
- Non programmable: always ON
- The alert is triggered when the device detects supply or shock impedance issue at the time it has to deliver the shock or in the event of too many strong EMI

LEAD ALERTS



Impedance

Right Ventricular Impedance

- Available in VR, DR and CRT-D
- Critical alert CRITICAL
- Programmable value: ON/OFF (as-shipped: ON)
  - Minimum programmable value: 200 to 500 ohms, 50 ohms steps
  - Max programmable value: 1500 – 1750 – 2000 – 2500 – 3000 ohms
- The right ventricular impedance is measured every 6 hours
- The alert is triggered when:
  - At least 3 right ventricular impedance measurements have been performed during the day and the average of the measurements is lower than the minimum RV impedance programmable value
  - Or at least 3 right ventricular impedance measurements have been performed during the day and the average of the measurements is higher than the maximum RV impedance programmable value
  - Or during 3 consecutive days, the minimum right ventricular impedance value measured during a day is lower than the minimum RV impedance programmable value
  - Or during 3 consecutive days, the maximum right ventricular impedance value measured during a day is higher than the maximum RV impedance programmable value

Right Atrial Impedance

- Available in DR and CRT-D
- Critical alert CRITICAL
- Same functioning as for right ventricular lead

Left Ventricular Impedance

- Available in CRT-D
- Critical alert CRITICAL
- Same functioning as for right ventricular lead and right atrial lead

Coil continuity

Right Ventricular Coil Continuity

- Available in VR, DR and CRT-D
- Critical alert CRITICAL
- Programmable value: ON/OFF (as-shipped: ON)
- The RV coil continuity is routinely measured every day by PLATINIUM, every week by PARADYM RF/INTENSIA
- The alert is triggered when the RV coil continuity measurement is higher than 3000 ohms during 2 consecutive days

Note: In PARADYM RF and INTENSIA, the RV coil continuity measurement is routinely performed once per week; in the event the RV continuity measurement is higher than 3000 ohms, the device performs a RV coil continuity measurement the day after. If the second measurement is also higher than 3000 ohms, the alert "RV coil continuity" is triggered.

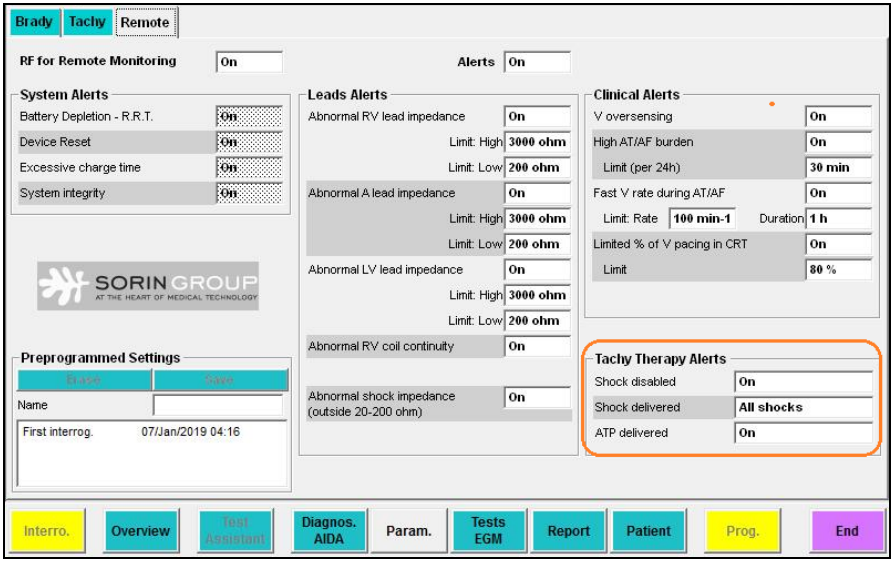
Superior Vena Cava Coil Continuity

- Available in VR, DR and CRT-D
- Critical alert CRITICAL
- Same functioning as for the RV coil

Abnormal shock impedance

- Available in VR, DR and CRT-D
- Highly critical alert CRITICAL
- Programmable: ON/OFF (as-shipped: ON)
- The shock impedance is measured after a shock is delivered.
- The alert is triggered when a shock has been delivered and the measured impedance is less than 20 ohms or more than 200 ohms

TACHY THERAPY ALERTS



Shock disabled

- Available in VR, DR and CRT-D
- Critical alert CRITICAL
- Programmable: ON/OFF (as-shipped: ON)
- The alert is triggered if the shocks are off at the end of the in-clinic session

Shock delivered

- Available in VR, DR and CRT-D
- Could be CRITICAL (highly critical alert) or SIGNIFICANT (clinical alert) according to the level of the alert
- Programmable: Off – All shocks – Inefficient shocks – Inefficient max shock (as-shipped: “All shocks”)
- “All shocks” includes “Inefficient shock” (clinical alert) and “inefficient max shock” (highly critical alert)
- Depending on the programming, the alert is triggered when a shock is delivered (“All shocks”), or an inefficient shock is delivered, or an inefficient max energy shock is delivered

Note: If the shock delivered is an inefficient high energy shock, the device will trigger the "inefficient max energy shock", see the next paragraph.

Inefficient Max energy shock

- Available in VR, DR and CRT-D
- Highly critical alert CRITICAL
- The alert is triggered when the device delivered at least one 42 J shock which was inefficient

ATP delivered

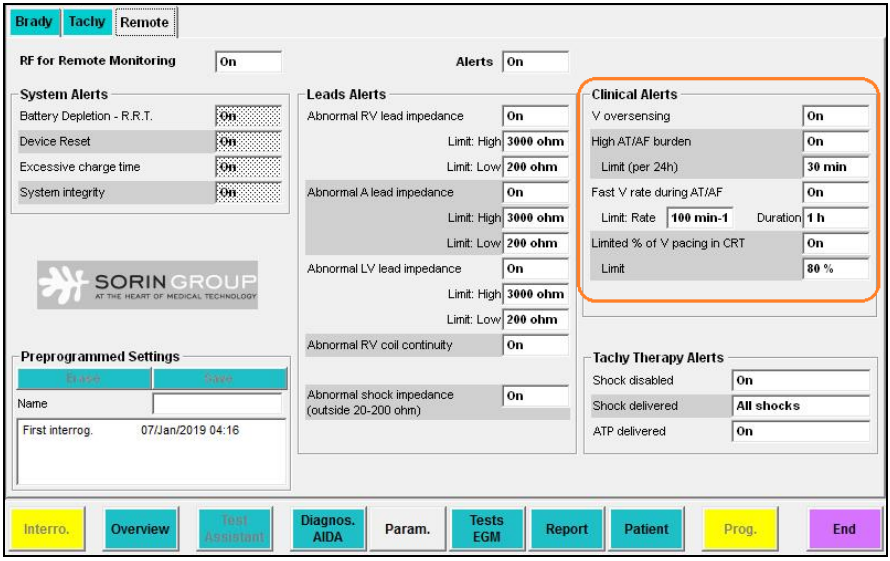
- Available in VR, DR and CRT-D
- Clinical alert SIGNIFICANT
- Only available on PLATINIUM models
- Programmable: OFF/ON (as-shipped: OFF)
  - Available only when "shock delivered" parameter is programmed to "All shocks"
- The alert is triggered when ATP is delivered

Note: if one shock occurs afterwards, the "shock alert" will be triggered instead of ATP alert.

Programming constraint

ATP alert can be programmed only if the "All shocks" alert is programmed.

CLINICAL ALERTS (SIGNIFICANT)



CRT – Percentage of daily V pacing

- Available in CRT-D when pacing chambers are L+R or R+L or L only and programmed mode is DDD or DDI or VVI
- Clinical alert SIGNIFICANT
- Programmable: OFF/ON (as-shipped: OFF)
  - When programmed ON, the Physician programs the threshold %: 50– 70– 80– 85– 90–95% (as-shipped: 80%)
- The alert is triggered when the percentage of ventricular pacing is lower for 24 hours than the programmed percentage for the alert

V noise

- Available in VR, DR and CRT-D
- Clinical alert SIGNIFICANT
- Programmable: OFF/ON (as-shipped: OFF)
- The alert is triggered when the device has already recorded at least 10 sustained VF/fast VT episodes (persistence was reached) and among them, 60% at least were not treated

High AT/AF burden

- Available in DR and CRT-D devices in DDD and SafeR mode when the atrial lead is implanted
- Clinical alert SIGNIFICANT
- Programmable: OFF/ON (as-shipped: OFF)
  - When programmed ON, the physician programs the limit per 24h in AT/AF to trigger the alert: 30 min – 1 h - 3 h - 6 h - 12 h - 24 h (as-shipped: 6 h)
- The alert is triggered when the device is functioning in mode switch for longer time than the programmed threshold time in 24 hours

Fast ventricular rate during AF/AT

- Available in DR and CRT-D devices when the atrial lead is implanted in DDD and SafeR modes
- Clinical alert SIGNIFICANT
- Programmable: OFF/ON (as-shipped: OFF)
  - When programmed ON, the physician programs the ventricular limit rate and the duration: Limit rate: 80 – 90 – 100 – 110 – 120 bpm (as-shipped: 100 bpm)
    Duration: 30 min – 1 h - 3 h - 6 h - 12 h - 24 h (as-shipped: 1 h)
- The alert is triggered when the device is functioning in mode switch for longer time than the programmed threshold time in 24 hours and if the ventricular rate during mode switch is higher than the programmed rate threshold

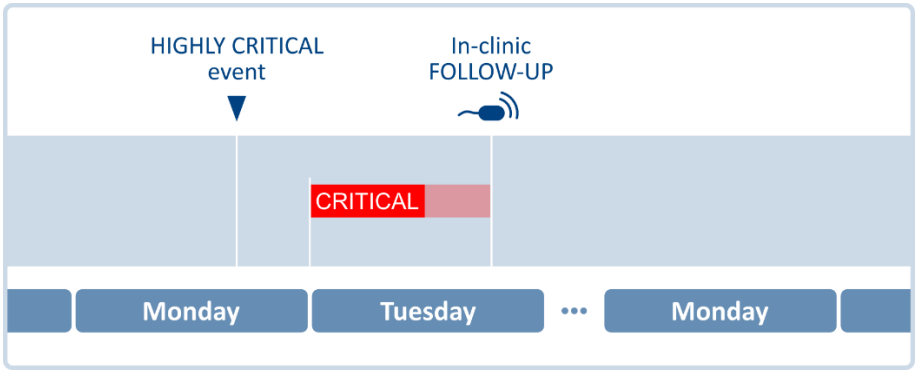
Highly critical event

Non recurrent event which requires in-clinic device follow-up (for example: device reset, charging time, device integrity, shock impedance, high energy shock): CRITICAL

- The alert is sent during the night following the event occurrence.
- If the same event occurs during the week after the first alert was sent and no in-clinic follow-up would have been performed since the first alert was sent, a second alert is sent (very rare case).
- If no in-clinic follow-up occurs during the week after the last alert was sent, the device sends a reminder to the center 7 days later.
- The same alert can only be sent two times and a reminder is sent between two in-clinic follow-ups.
- Any in-clinic follow-up resets the number of occurrences.

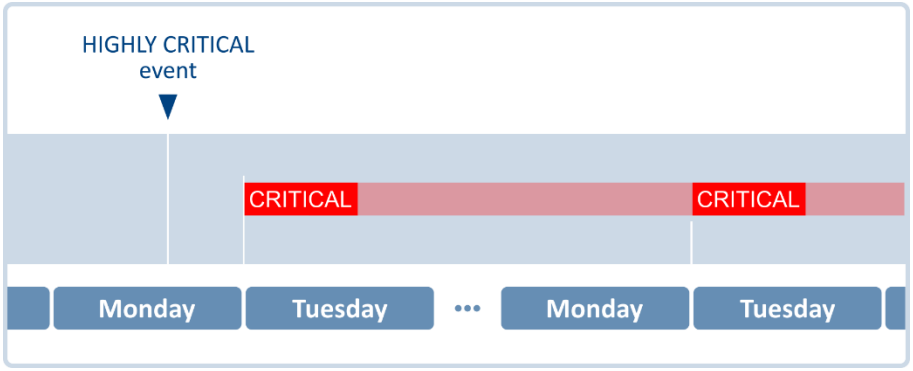
Example 1

A highly critical alert is sent and the patient goes to the center the day after. In-clinic follow-up is performed. No reminder will be sent after 7 days because in-clinic follow-up has occurred and the counters of alerts are reset at the end of the follow-up.



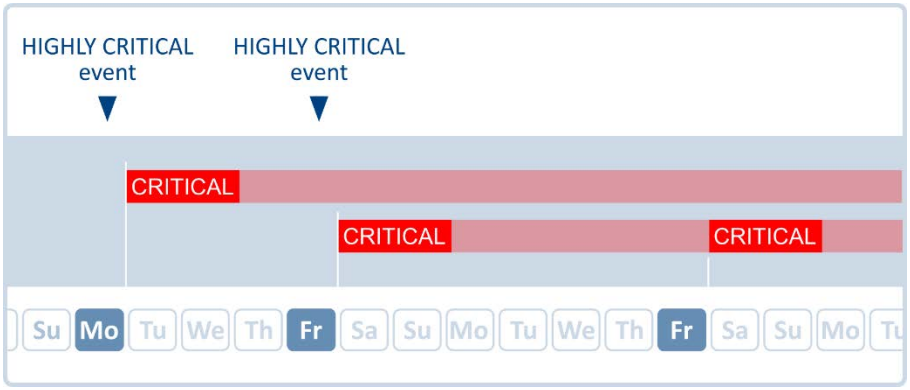
Example 2

A highly critical alert is sent and the patient does not go to the center. A reminder is sent to the center one week later to inform the physician that this is a highly critical alert and that the patient/device follow-up is mandatory.



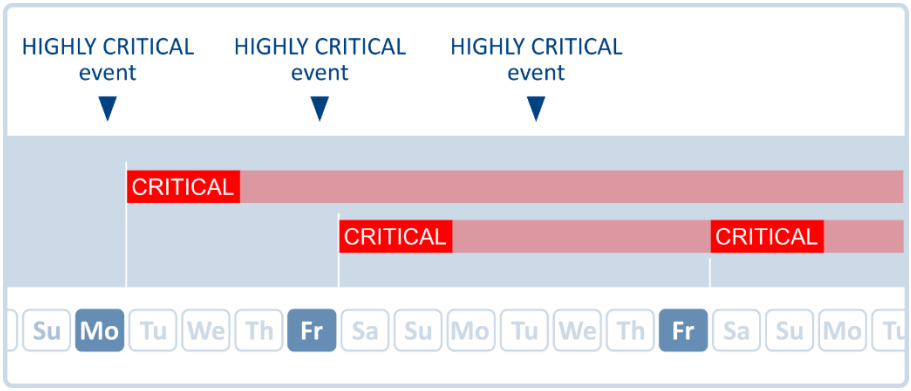
Example 3

A highly critical alert is sent and the patient does not go to the center. 4 days later, the same event occurs: a second occurrence of this alert is sent. The patient still does not go to the center: a reminder is sent to the center 7 days after the second alert to inform the center that this is a highly critical alert and that the patient/device follow-up is mandatory.



Example 4

A highly critical alert is sent and the patient does not go to the center. 4 days later, the same event occurs: a second occurrence of this alert is sent. The patient still does not go to the center. 4 days later, the same event occurs for the third time: the alert is not sent because the device only sends 2 alerts of the same highly critical event. The patient still does not go to the center: a reminder is sent to the center 7 days after the second alert to inform the center that this is a highly critical alert and that the patient/device follow-up is mandatory.



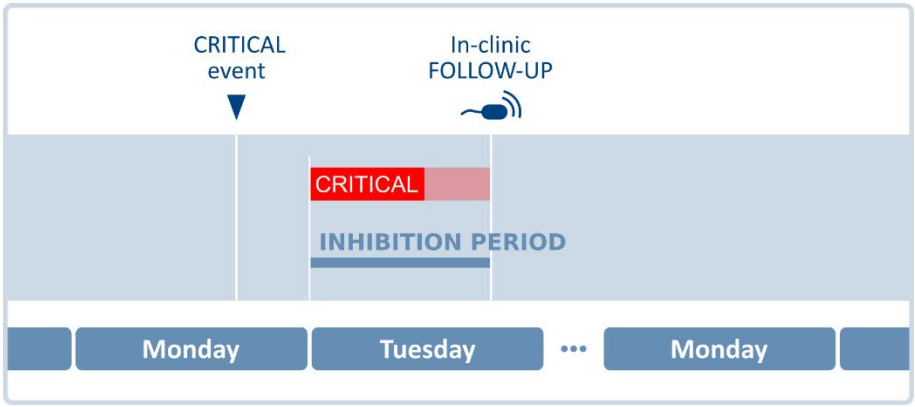
Critical event

Recurrent event which requires in-clinic device follow-up: CRITICAL

- The alert is sent during the night following the event occurrence.
- Then the device applies a 7 day-inhibition period for sending this alert in order to avoid this recurrent alert to be sent every day until the patient goes to the center. After 7 days and if no in- clinic follow-up was performed since the first alert was sent and if the device still detects the alert, the alert will be sent for the second time.
- The same alert can only be sent two times between two in-clinic follow-ups.
- No reminder after 7 days for the critical alerts.
- Any in-clinic follow-up resets the number of occurrences.

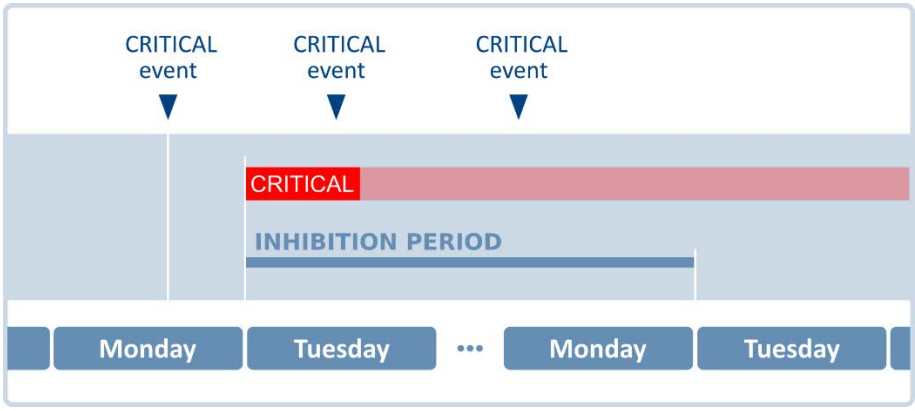
Example 1

A critical alert is sent and the patient goes to the center the day after. In-clinic follow-up is performed. The counters of alerts are reset at the end of the follow-up.



Example 2

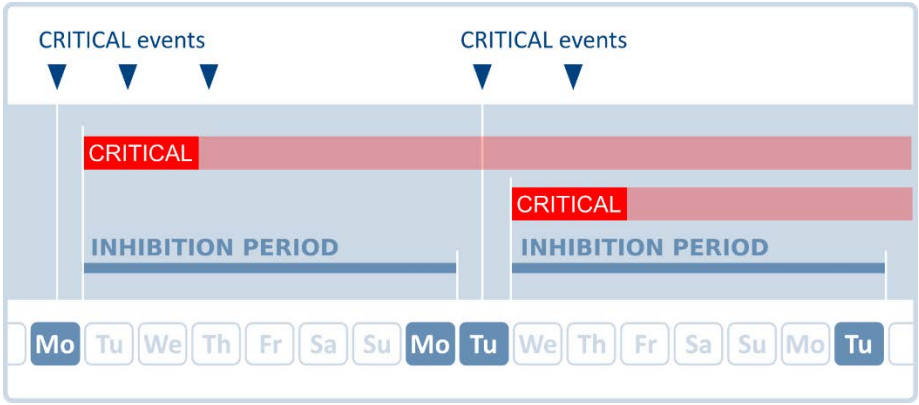
A critical alert is sent and the patient does not go to the center for one week. Occurrences of the same alert during the same week are not sent (7-day inhibition period).



Note: If the alert still occurs one week after the first alert was sent, the alert is sent for the second time. The patient has to be contacted to go to the center to solve this issue.

Example 3

A critical alert is sent and the patient does not go to the center for one week. Occurrences of the same alert during the same week are not sent (7-day inhibition period). As the alert still occurs one week after the first alert was sent, the alert is sent for the second time. When it occurs again, it will not be sent anymore even after the 7-day inhibition period: the patient should have been to the center to solve this issue.



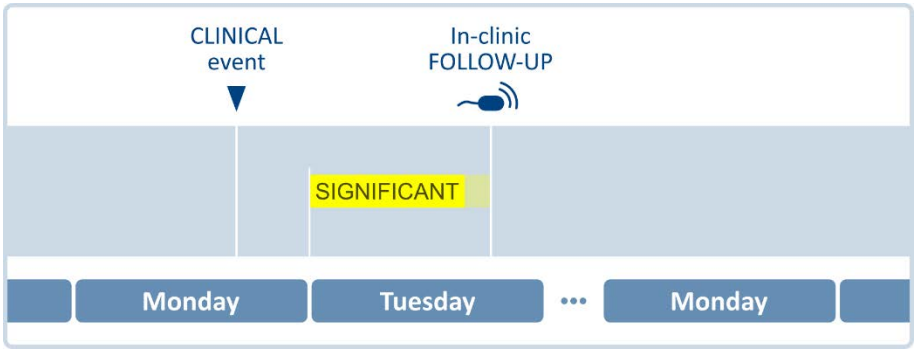
Clinical event

Recurrent event which may require in-clinic device follow-up: SIGNIFICANT

- The alert is sent during the night following the event occurrence.
- Between two in-clinic follow-ups, the same alert can be sent:
  - two times per type of event for “ventricular oversensing”, “high AT/AF burden”, “fast V rate during AT/AF” and “limited % of V pacing in CRT”
  - 8 times per type of event for the ATP and shock delivery
- No reminder after 7 days and no inhibition period for the clinical alerts.
- Any in-clinic follow-up resets the number of occurrences.

Example 1

A clinical alert is sent and the patient goes to the center the day after. In-clinic follow-up is performed. The counters of alerts are reset at the end of the follow-up.



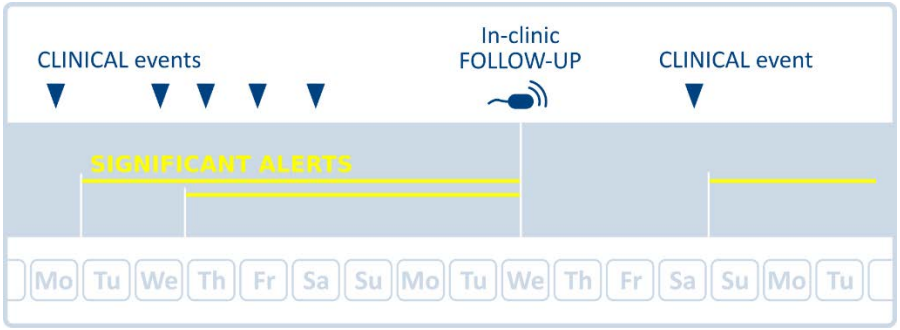
Example 2

A clinical alert is sent and the patient does not go to the center for one week. Occurrences of the same alert will be sent:

- One more time for “Ventricular oversensing”, “High AT/AF burden”, “Fast V rate during AT/AF” and “Limited % of V pacing in CRT” (example 2A)
- Up to seven more times for ATP and shock delivery (example 2B)

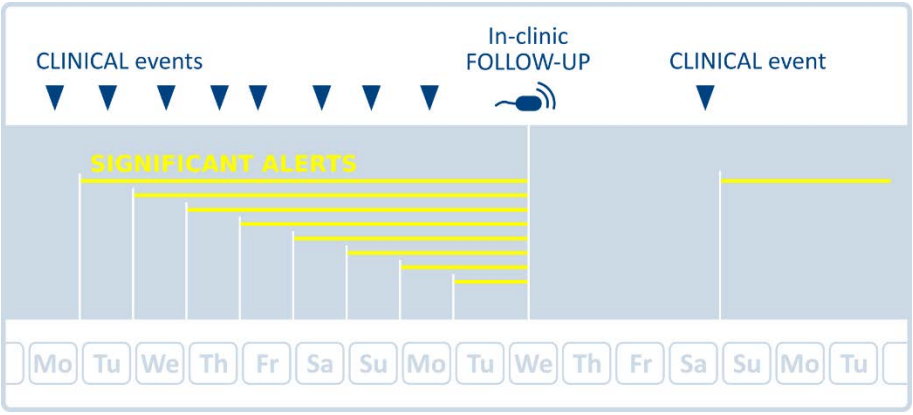
When in-clinic follow-up is performed, the counters of alerts are reset at the end of the follow-up.

Example 2A



CLINICAL event = Ventricular oversensing, High AT/AF burden, Fast V rate during AT/AF, Limited % of V pacing in CRT

Example 2B



CLINICAL event = ATP or Shock delivery

On the programmer, the date of the alert will correspond to the last occurrence, even when not sent through the remote monitoring system.