## Pump Event Information
### SynchroMed® II Battery Performance

<table>
<thead>
<tr>
<th>Event</th>
<th>What it means</th>
<th>Type of Alarm</th>
<th>Therapeutic Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Battery Reset</td>
<td>LBR occurs when battery voltage momentarily drops below 1.975 volts. If the voltage drop causes any data loss or corruption in pump memory, a <em>safe state</em> event will be triggered, resulting in infusion at the minimum rate mode of 6 microliters/day (0.006 milliliters/day) rather than the previously programmed rate. Although you may be able to reprogram the pump, the issue may reoccur at any time.</td>
<td>Critical</td>
<td>If safe state is triggered, the pump will go into minimum rate mode: 6 microliters/day (0.006 milliliters/day) rather than the previously programmed rate. The minimum rate mode in effect during a pump <em>safe state</em> is non-therapeutic and can result in loss of drug effect and drug withdrawal.</td>
</tr>
<tr>
<td>Elective Replacement Indicator</td>
<td>ERI activates when the pump nears the end of its service life (EOS). At ERI, the pump continues to infuse at the programmed rate.</td>
<td>Non-Critical</td>
<td>A normal pump will operate for a minimum of 90 days at rates up to 1.5 mL/day prior to EOS. In the case of premature ERI**, the minimum timeframe of 90 days between ERI and EOS may be reduced. This means that the date for scheduled replacement of the pump that is displayed on the N’Vision® Model 8840 clinician programmer may not be accurate.</td>
</tr>
<tr>
<td>End Of Service</td>
<td>EOS activation indicates the pump has reached the end of its service life. At EOS, the pump permanently stops infusing, but telemetry is available until the pump battery is depleted.</td>
<td>Critical</td>
<td>Pump will permanently stop delivering drug.</td>
</tr>
</tbody>
</table>

*Note: *safe state* does not mean a clinically safe rate of infusion. The minimum rate mode in effect during a pump *safe state* is non-therapeutic and can result in loss of drug effect and/or drug withdrawal. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not promptly and effectively treated.*

**Note: ERI may be considered premature if it occurs sooner than expected based on implant duration and flow rate. Contact Medtronic Technical Services (1-800-707-0933) for assistance determining if an ERI message can be considered premature.
Low Battery Reset

8840 N’Vision Programmer Screen

[Attention Dialog Box]

8840 Dialog Box – Notification for reset to safe state

[Pump Status Screen]

8840 Pump Status – Shows pump in safe state, and Infusion mode at “Minimum Rate”

8840 N’Vision Programmer Printouts

[Print Report]

Print Report
8840 Synchromed II & B Programming Session
Current Pump Settings
Examined At
05/07/2009
Last Change
05/07/2009
Pump In Safe State
Reset Occurred
Patient Information

[Event Log]

Event Log -- Specifies it was a Low Battery Reset

Print Report -- Shows “Reset Occurred”

Safe state does not mean a clinically safe rate of infusion. The minimum rate mode in effect during a pump safe state is non-therapeutic and can result in loss of drug effect and/or drug withdrawal.
Elective Replacement Indicator

**8840 N’Vision Programmer Screen**

- **Attention Dialog Box**
  - 8840 Dialog Box – Notification of ERI with calculated 90 day replacement date

- **Pump Status Screen**
  - 8840 Pump Status – Shows ERI Occurred, and calculated 90 day window to EOS

**8840 N’Vision Programmer Printouts**

- **Print Report**
  - Print Report – Shows ERI Occurred, and calculated 90 day window to EOS

- **Event Log**
  - Event Log – Specifies ERI Occurred

The minimum timeframe of 90 days between ERI and EOS may be reduced in an affected pump; therefore the scheduled replacement date displayed on the Print Report may not be accurate.
At EOS, the pump stops infusing drug. This will result in loss of drug effect and/or potentially drug withdrawal. Telemetry is available until the pump battery is depleted.