

## New Information Regarding Potential MRI Effects

<b>New Information</b>	<b>SynchroMed EL</b>	<b>SynchroMed II</b>
Delay in Return of Proper Infusion after an MRI	X	X
Event Logging Delay		X
Time Required for Stall & Recovery Detection		X

### **Delay in Return of Proper Infusion after an MRI**

Exposure to the MRI magnetic field may cause the motor gears within the pump to bind temporarily without permanent damage. This is caused by the potential for backward rotation of the pump rotor magnet when it aligns with the MRI magnetic field. This temporary binding may delay the return of proper infusion after the pump is removed from the MRI magnetic field.

### **Delay in Logging of Motor Stall Events (Event Logging Delay)**

The SynchroMed II pump checks for motor stall and motor stall recovery. These stall and recovery events are logged in the memory of the device. In some cases, electromagnetic interference (EMI) from the MRI may cause the pump to switch into the telemetry mode. 'Telemetry mode' is a special state in which the pump is able to communicate with the clinical programmer. While in this state, the pump infuses normally; however, some error logging and the audible alarm for motor stall are suspended. If the pump switches into telemetry mode due to EMI, the pump resumes drug delivery after leaving the MRI magnetic field; however, pump motor stall and motor stall recovery detection function is not active until the post MRI pump interrogation ends telemetry mode. Please note that due to this issue, if the interrogation is not performed upon completion of the MRI scan or shortly thereafter as indicated in the labeling, review of the pump logs may indicate that the pump ceased drug delivery for an extended period of time, when in fact it had recovered normally. In this scenario, you may receive an erroneous “stopped pump period may exceed tube set” error message.

### **Delay in Logging of Motor Stall Events (Time Required for Stall & Recovery Detection)**

The SynchroMed II pump audibly alarms (two-tone) in the event of a motor stall. For pumps programmed to deliver at least 0.048 ml/day, the motor stall detection (with audible alarm) should occur within 20 minutes of exposure to the MRI magnetic field. Stall recovery detection should occur within 20 minutes of exiting the MRI magnetic field. Please note that the slower the programmed delivery rate is, the longer it may take for the stall detection algorithm to log motor stall and/or motor recovery (both the detection of a motor stall and detection of motor stall recovery may each take up to 90 minutes if the pump is programmed to minimum rate mode (0.006 ml/day)).