

**SynchroMed®**  
**Important Information on Potential MRI Effects**

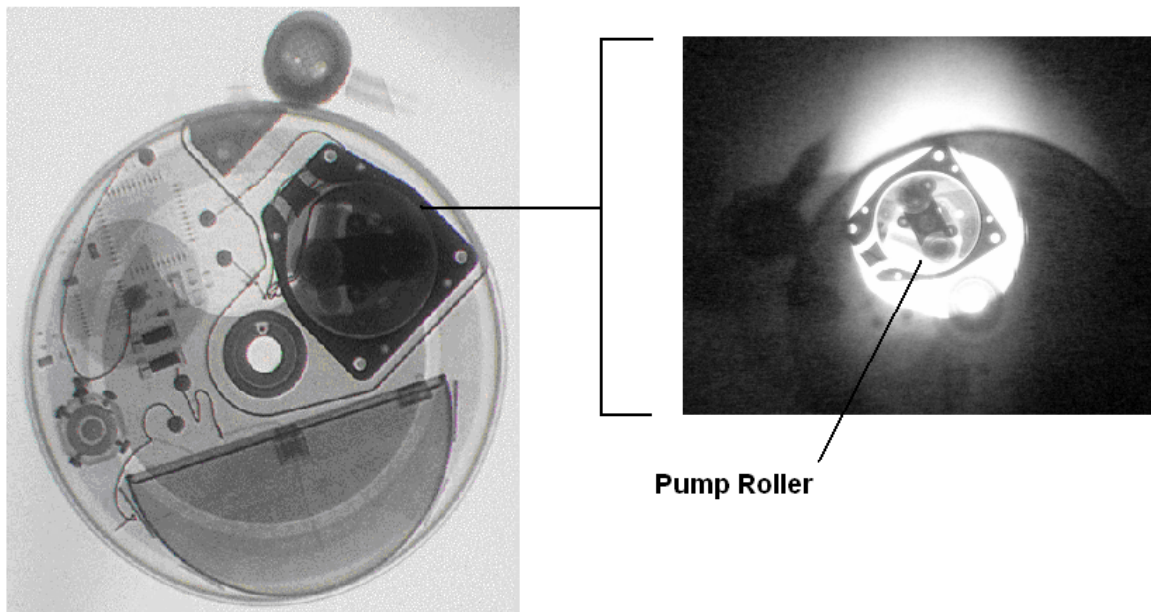
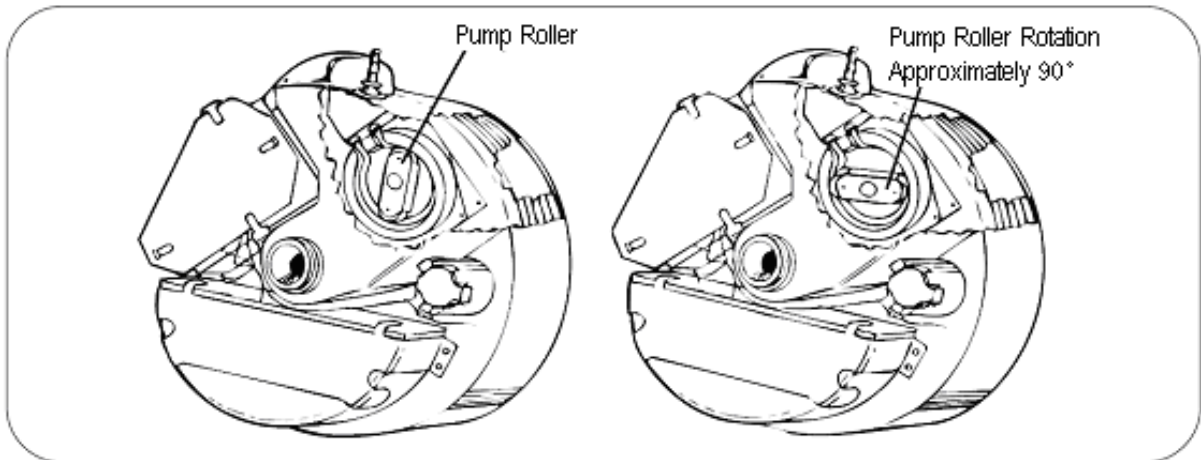
**Roller Study Procedure**

---

**Roller Study Procedure – SynchroMed EL**

To confirm pump function, conduct a roller study using this procedure. Review the following procedure carefully before beginning:

1. X-ray the pump to determine the location of the pump roller (overexposing the film will make the roller more visible). Several attempts may be necessary to visualize the roller.



2. Only use a Medtronic catheter access port (CAP) kit to access the catheter access port septum.
3. Calculate the amount of a bolus in microliters ( $\mu\text{L}$ ) that will move the roller approximately  $90^\circ$ . Use the formula below.

a.	<b>Determine the calibration constant from the Pump Status Screen of the programmer or patient's <i>Implanted Device Identification</i> card.</b>
b.	<b>Divide 1800 by the calibration constant.</b> The result is the volume in $\mu\text{L}$ required to move the roller approximately $90^\circ$ . $1800 \div \text{Cal Constant} = \text{_____} \mu\text{L}$
c.	To obtain the bolus dose expressed in the present metrology, <b>multiply the formula's result (in <math>\mu\text{L}</math>) by the concentration, and divide by 1000.</b> $\frac{\mu\text{L} \times (\text{drug concentration})}{1000 \mu\text{L/mL}} = \text{Dose in Present Metrology}$

**WARNING**

A significant amount of drug may be present in the catheter access port and catheter. Failure to remove the drug during catheter access port injections can result in clinically significant or fatal drug overdose.

4. If the calculated bolus could cause an overdose, aspirate approximately 1-2 mL of fluid from the catheter access port to ensure removal of drug from the catheter access port and catheter.
5. Program a single bolus using the calculated dose to run for approximately 1 minute. The pump will operate for approximately 1 minute to deliver a bolus that will turn the roller approximately  $90^\circ$ .
6. X-ray the pump and determine the new position of the pump's roller. The pump's roller should have moved approximately  $90^\circ$ . Alternatively, fluoroscopy can be used to visualize the pump as it moves to its new position.
7. If there is no roller movement, the device may be stalled. Make copies of the pump status after update printout and the x-rays, then contact Medtronic, Inc. or your local Medtronic Representative.
8. Subsequent to a pump roller study, the appropriate priming bolus must be performed per the implant manual to advance the drug to the catheter tip.

**NOTE:** If drug was aspirated from the CAP prior to the roller study, both the volume of drug that was aspirated from the CAP and the roller study bolus should be taken into consideration when performing the priming bolus.

**WARNING**

Programming a bolus could lead to drug overdose. Therefore, caution must be used when calculating and programming all bolus doses.