

**SynchroMed® II Implantable Infusion Pump (Models 8637-20 and 8637-40)
Missing Propellant Physician Letter – Enclosure**

How to Identify Pumps Without Propellant

How to Identify Non-Implanted Pumps Without Propellant:

Medtronic recommends careful adherence to pre-implant pump preparation instructions set forth in the labeling. If a discrepancy is noted when aspirating the pump, followed by the inability to fill the pump to capacity, the device should not be used, and should be returned to Medtronic for analysis.

Expected Aspiration Volume: (Note: this volume is variable based on the product shelf life because the pump continually dispenses 0.006ml/day from the date of manufacture)

- 20 ml pump, at least 16.1 +/- 0.5 ml (less 0.18 ml for each month beyond manufactured date)
- 40 ml pump, at least 36.1 +/- 0.5 ml (less 0.18 ml for each month beyond manufactured date)

Expected Fill Volume (completely full)

- 20 ml pump, at least 18 ml
- 40 ml pump, at least 36 ml

How to Identify Implanted Pumps Without Propellant:

Pumps without propellant may be identified during clinical follow up by reviewing the patient's clinical history and evaluating the reservoir volume. Physicians should use their medical judgment in considering prioritization of patient follow-up based on therapy and associated withdrawal risks. The patient's clinical history should be reviewed for the following conditions:

Implanted Pump Identification Conditions

▪ When programmer reservoir volume is less than 25% of actual reservoir volume.
▪ Inability to aspirate the expected reservoir volume when removing all fluid from the reservoir.
▪ Subsequent to complete reservoir volume aspiration, full pump reservoir capacity cannot be filled. <ul style="list-style-type: none">○ 20 ml pump, inability to fill > 18 ml○ 40 ml pump, inability to fill > 36 ml

If **all** of the conditions identified above are identified during the review of the patient history, Medtronic recommends performing the following troubleshooting procedures immediately.

- Perform a complete aspiration of the pump reservoir
- Perform a complete fill of the pump reservoir

If the expected amount (20ml in the 8637-20 or 40ml in the Model 8637-40) of drug cannot be injected into the pump, this pump may not contain propellant. Medtronic Technical Services should be contacted for additional troubleshooting support.

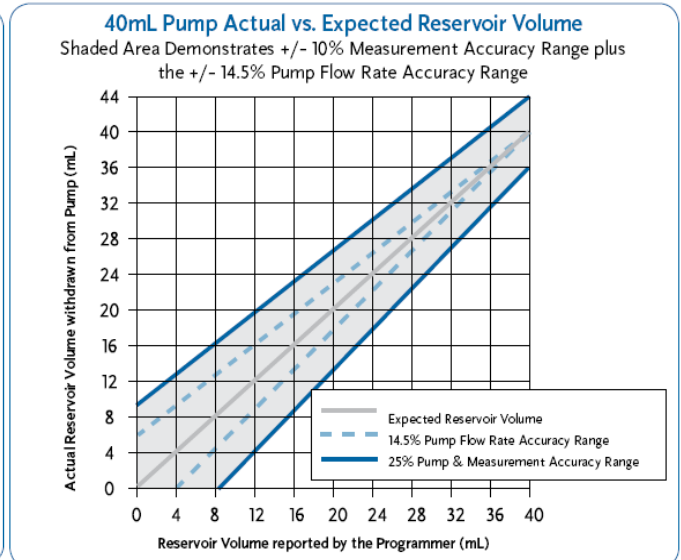
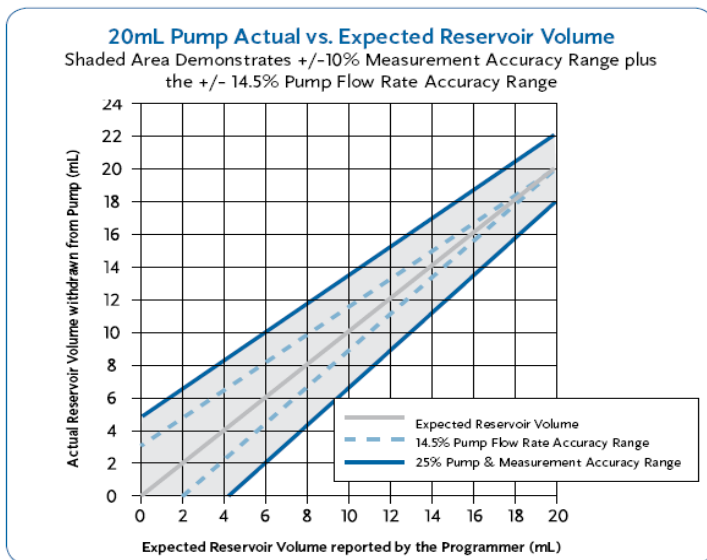
Reservoir volume percent error calculations:

The following describes the calculations used for performing pump reservoir volume percent error calculations, along with error measurement guidelines. This information can also be found in the SynchroMed II Clinical Reference Guide.

Compare the actual residual volume with the expected residual volume (reservoir volume reading from the initial interrogation).

$$\% \text{ Error} = \frac{(\text{Expected Residual Volume in mL} - \text{Actual Residual Volume in mL})}{(\text{Previous Refill Volume} - \text{Expected Residual Volume})} \times 100$$

If necessary, use the Flow Rate Accuracy Charts below to help determine if a residual volume is within the error measurement guidelines.



NOTE:

The manufacturing specifications of the SynchroMed II pump require the flow rate to be $\pm 14.5\%$ of the programmed rate. However, clinical measurements can vary from the programmed rate due to errors in syringe measurement accuracy, human error, and the volume of prescribed fluid in the extension tubing and filter. Therefore, $\pm 25\%$ flow rate error is the guideline for determining a significant discrepancy.