

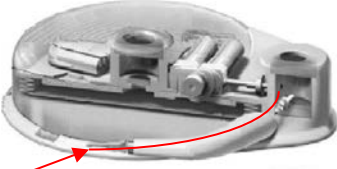
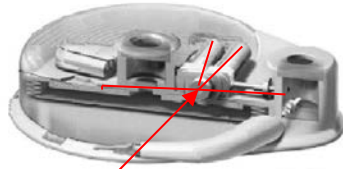

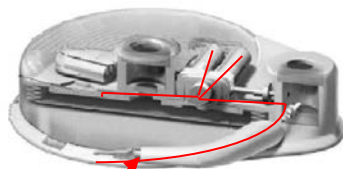
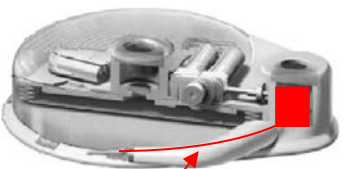


## CALCULATIONS GUIDE

For use with Intrathecal Catheter & Prometra Programmable Pump



### Pump Fluid Volumes Easy Reference

Non-CAP Measurements	CAP Measurements
 <p>Pump Stem Volume: 0.068 mL</p>	
 <p>Precision Dosing System Volume: 0.137 mL The PDS Volume is the volume from the filter to the CAP</p>	 <p>Catheter Access Port Chamber Volume: 0.191 mL</p>
 <p>Fluid Pathway Volume = Dosing Chamber Volume + Pump Stem Volume 0.205 mL = 0.137 mL + 0.068 mL (The Fluid Pathway is the volume that goes from the filter to the distal pump stem.)</p>	 <p>Catheter Access Port Fluid Pathway Volume = Catheter Access Port Chamber Volume + Pump Stem Volume 0.259 mL = 0.191 mL + 0.068 mL (The Catheter Access Port Fluid Pathway Volume is the volume that goes from the Catheter Access Port Chamber to the distal tip of the pump stem.)</p>

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

For Indications, Contraindications, Warnings, Precautions and potential adverse events related to the Prometra Pump, refer to the Prometra Programmable Pump Physician's Manual.

Constants	Abbreviation	Value	Definition
Maximum Delivery Rate	Max Del Rate	0.02 mL/min	The maximum rate at which the pump can deliver drug.
Pump Stem Volume	Pump Stem Volume	0.068 mL	The volume in the Pump Stem connecting the pump dosing chamber with the catheter.
Implanted Catheter Volume	Impl Cath Vol	0.0026 mL/cm	The implanted catheter volume per centimeter
Precision Dosing System Volume	PDS Volume	0.137 mL	The volume from the filter to the CAP
Fluid Pathway Volume	Fluid Path Volume	0.205 mL	The total volume from the filter to the distal end of the pump stem. It includes the PDS volume and the Pump Stem volume.
Reservoir Residual Volume	Reservoir Residual Volume	3 mL	The volume of fluid left within the drug refill reservoir after emptying.
Catheter Access Port Chamber Volume	CAP Volume	0.191 mL	The volume in the catheter access port chamber beneath the catheter access port septum.
Catheter Access Port Fluid Pathway Volume	CAP Fluid Path Volume	0.259 mL	The total volume from the catheter access port chamber to the distal end of the Pump Stem. It includes the catheter access chamber port volume and the Pump Stem volume.

Term	Abbreviation	Definition
New Drug Concentration (mg/mL)	New Concentration	The concentration of the drug from the current pump refill procedure.
Old Drug Concentration (mg/mL)	Old Concentration	The concentration of the drug from the previous pump refill procedure.
Refill Syringe Concentration (mg/mL)	Refill Concentration	The drug concentration required in the refill syringe to achieve the desired patient dose. If changing drug concentration, this takes in consideration the residual volume of Old Drug Concentration.
Refill Volume (mL)	Refill Volume	The volume infused into the reservoir during a refill procedure.
Bridge Bolus	Bridge Bolus	A transitional dose and duration to ensure that the patient is receiving the new changed drug concentration or solution at the prescribed dose. The bridge bolus takes into consideration the old drug concentration being cleared from the pump and catheter fluid pathway before the new programmed regimen takes over.
Targeted Daily Rate (mg/day)	Targeted Daily Rate	The desired daily dose rate for the patient.

For low concentrations: Concentrations and Dosages can be expressed in mcg/mL and mcg. In order to convert from mcg to mg, you must divide the microgram dose by 1,000. For example, a dose of 50 mcg becomes 50 / 1000 or 0.05 mg. A concentration of 500 mcg/mL becomes 500 / 1000 or 0.5 mg/mL.

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These devices may be covered by one or more patents or pending patent applications. Refer to instructions for use for complete prescribing information, including warnings, cautions, and contraindications.

Please consult [www.infusyn.com](http://www.infusyn.com) for the most up-to-date information.

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## Variable Values and Terminology

Term	Abbreviation	Definition	When Used	Calculation	Example (all examples use 60cm Implanted Cath Length)
Implanted Catheter Length (cm)	Impl Cath Lgth	The length of catheter implanted in patient, after trimming. This is determined by subtracting the length of the trimmed portion of catheter from the total catheter length.	Used to calculate the Implanted Catheter Volume, which is in turn used in nearly all other calculations.	Can be found in patient records or the patient ID card	Can be found in patient records or the patient ID card
Implanted Catheter Volume (mL)	Impl Cath Vol	The infusate volume in the implanted catheter. This volume is dependent on the implanted catheter length.	Used in nearly all other calculations.	Impl Cath Vol = Implanted Cath Length (cm) x 0.0026 (mL)	Impl Cath Vol = 60 cm x 0.0026 mL = 0.156 mL
Reservoir Residual Correction Factor	CF	The correction factor applied to the Refill Volume to correct for dose present in the Reservoir Residual Volume.	When changing infusate concentration.	CF = 3(mL) / Refill Vol. (mL)	CF = 3 / 20 = 0.15

## Calculations

Term	Definition	When Used	Calculation	Example (all examples use 60cm implanted Cath length)	
At Implant	Post-op Priming Bolus	Request pump to bolus infusate remaining in the PDS and Pump Stem. This is done by programming the pump with the required dose and duration.	Generally used at implant to begin therapy and push infusate to the tip of the catheter at the maximum rate.	Dem Bolus Dose (mg) = (Impl Cath Vol (mL) + Fluid Path Vol (mL)) * New Conc (mg/mL) Dem Bolus Duration (min) = (Impl Cath Vol (mL) + Fluid Path Vol (mL)) / Max Del Rate (mL/min)	Assuming New Conc = 8 mg/mL, Target D Rate = 2 mg Dem Bolus Dose = (0.156 + 0.205) * 8mg/mL = 2.89 mg Dem Bolus Duration = (0.156 + 0.205) / .02 = 19 min. (rounded up)
Not at Implant	Manual Bolus Dose Injection/Flushing	Manual bolus of infusate remaining in the catheter access chamber, pump Pump Stem and intrathecal catheter. This is the dose received by the patient if the CAP is not already aspirated.	When determining the dose of infusate that the patient will receive if the catheter is not already aspirated.	Man Bolus (mg) = (Impl Cath Vol (mL) + CAP Fluid Path Vol (mL)) * Old Conc (mg/mL)	Assuming Old Conc = 8 mg/mL Man Bolus = (0.156 + 0.259) * 8mg/mL = 3.32 mg
Change Drug Conc.	<b>Changing Drug Conc. (without aspiration)</b>				
	Refill Syringe Concentration	This calculation is used to determine the optimal refill syringe drug concentration. The calculation corrects for the infusate at old concentration that cannot be removed from the pump.	When drug concentrations are to be changed, use this calculation to determine the desired concentration for the drug in the refill syringe.	Refill Syringe Conc (mg/mL) = [(New Conc (mg/mL) – Old Conc (mg/mL)) x CF + New Conc (mg/mL)]	Assuming Refill Vol = 20mL New Conc = 12mg/mL Old Conc = 8mg/mL Refill Syringe conc (mg/mL) = ((12 – 8) * 0.15 + 12) = 12.6 mg/mL
C A P	<b>Changing Drug Conc. (with aspiration)</b>				
	Catheter Aspiration Volume	A calculation of the volume of infusate that should be pulled from the port's CAP in order to removed infusate from the implanted catheter and the pump's catheter access port fluid pathway.	When aspirating the catheter. Often for myelography, dye studies, or flushing the catheter.	Aspirate Volume = Impl Cath Vol (mL) + CAP Fluid Path Vol	Aspirate Vol = 0.156 + 0.259 = 0.415 mL
	Refill Syringe Concentration	This calculation is used to determine the optimal refill syringe drug concentration. The calculation corrects for the infusate at old concentration that cannot be removed from the pump.	When drug concentrations are to be changed, use this calculation to determine the desired concentration for the drug in the refill syringe.	Refill Syringe Conc (mg/mL) = [(New Conc (mg/mL) – Old Conc (mg/mL)) * CF + New Conc (mg/mL)]	Assuming Refill Vol = 20mL New Conc = 12mg/mL Old Conc = 8mg/mL Refill Syringe conc (mg/mL) = ((12 – 8) * 0.15 + 12) = 12.6 mg/mL
	Bridge 1 Bolus Bridge 1 Duration	The first bridge bolus rapidly advances the new concentration into the catheter to prepare for the second bridge bolus which will begin delivering the new therapy.	When drug concentrations are changed, use this calculation to determine the dose and duration for programming the first Bridge Bolus and duration.	Bridge 1 Dose = [Pump Stem Vol (mL)+ Impl Cath Vol (mL)] * New Conc Bridge 1 Duration = [Pump Stem Vol (mL)+ Impl Cath Vol (mL)] * Max Del Rate	Assuming New Conc = 12 mg/mL Bridge 1 Dose = (0.068 (mL) + 0.156 (mL)) * 12 (mg/mL) = 2.688 mg Bridge 1 Duration = ((0.068 (mL) + 0.156 (mL)) * .02 = 12 minutes (rounded up)
Bridge 2 Bolus Bridge 2 Duration	The second bridge bolus is programmed to deliver the required volume of new drug to immediately achieve the new targeted dose.	When drug concentrations are changed, use this calculation to determine the dose and duration for programming the second Bridge Bolus and duration.	Bridge 2 Dose = [PDSVol (mL) * Old Conc (mg/mL)] * New Conc (mg/mL) / Old Conc (mg/mL) Bridge 2 Duration = Old Conc Dose (mg) / [Targeted Dose (mg/day) / 24 hr/day]	Assuming Old Conc = 8 mg/mL Targeted Dose = 6 mg/day Bridge 2 Dose = (0.137 mL * 8 (mg/mL)) * 12 (mg/ml) / 8 (mg/mL) = 1.644 (mg) Bridge 2 Duration = (0.137 (mL) * 8 (mg/mL)) / (6 (mg/day) / 24 (hr/day)) = 4.384 hr, or 4 hours, 23 minutes	