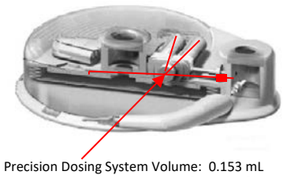
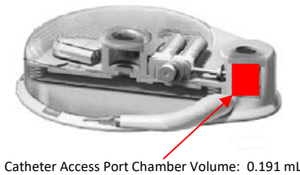
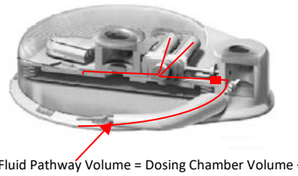
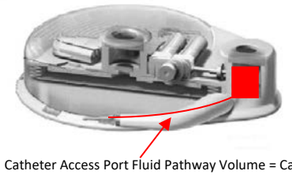
prometra® II programmable pump

CALCULATIONS GUIDE

For use with Intrathecal Catheter & Prometra II Programmable Pump

Pump Fluid Volumes *Easy Reference*

Non-CAP Measurements	CAP Measurements
 Pump Stem Volume: 0.068 mL	
 Precision Dosing System Volume: 0.153 mL The PDS Volume is the volume from the filter to the CAP	 Catheter Access Port Chamber Volume: 0.191 mL
 Fluid Pathway Volume = Dosing Chamber Volume + Pump Stem Volume 0.221 mL = 0.153 mL + 0.068 mL (The Fluid Pathway is the volume that goes from the filter to the distal pump stem).	 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.)

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 II Pump, refer to the Prometra II 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	0.153 mL	The volume from the filter to the CAP
Fluid Pathway Volume	Fluid Path Volume	0.221 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: Dosages can be expressed in micrograms (mcg) and concentrations can be expressed in micrograms per milliliter (mcg/mL). In order to convert from micrograms (mcg) to milligrams (mg), you must divide the microgram dose by 1,000 mcg/mg. For example, a dose of 50 mcg becomes (50 mcg) / (1000 mcg/mg) or 0.05 mg.
A concentration of 500 mcg/mL becomes (500 mcg/mL) / (1000 mcg/mg) or 0.5 mg/mL.

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 for the most up-to-date information.

Manufactured for:
Infusyn Therapeutics
121 Shelley Drive, Suite 2H
Hackettstown, NJ 078240 USA
T 973.426.9229
F 973.426.0035
www.infusyn.com

INFUSYN THERAPEUTICS

Issue Date: August 2024
PL-31700-01

Variable Values and Terminology

Term	Abbreviation	Definition	When Used	Calculation	Example (all examples use 60cm Impl Cath Length)
Implanted Catheter Length (cm)	Impl Cath Length	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 Volume	The infusate volume in the implanted catheter. This volume is dependent on the implanted catheter length.	Used in nearly all other calculations.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\left(\frac{mL}{cm}\right)$	Assuming Impl Cath Length = 60cm $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156mL$
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.	$CF = \frac{3mL}{Refill\ Volume\ (mL)}$	Assuming Refill Volume = 20 mL $CF = \frac{3mL}{20mL} = 0.15$

Calculations

	Term	Definition	When Used	Calculation	Example (all examples use 60cm Implanted Catheter Length)
At Implant	Post-op Catheter Priming Bolus	When the catheter is filled with saline or CSF, this catheter priming bolus may be used to request pump to bolus infusate to prime the Implanted Catheter Volume. 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.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\left(\frac{mL}{cm}\right)$ $Demand\ Bolus\ Dose\ (mg) = Impl\ Cath\ Volume(mL) * New\ Drug\ Concentration\left(\frac{mg}{mL}\right)$ $Demand\ Bolus\ Duration(\min) = \frac{Impl\ Cath\ Volume(mL)}{Maximum\ Delivery\ Rate\ \left(\frac{mL}{\min}\right)}$	*Assuming Impl Cath Length = 60 cm, New Concentration = 8 mg/mL* $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156mL$ $Demand\ Bolus\ Dose\ (mg) = (0.156\ mL) * 8\left(\frac{mg}{mL}\right) = 1.248\ mg\ \approx 1.25\ mg$ $Demand\ Bolus\ Duration(\min) = \frac{0.156\ mL}{0.02\ \left(\frac{mL}{\min}\right)} = 7.8\ min\ \approx 8\ min\ (when\ rounded\ up)$
Not at Implant	Manual Bolus Dose Injection/Flushing	Manual bolus of infusate remaining in the catheter access chamber, 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.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\left(\frac{mL}{cm}\right)$ $Manual\ Bolus\ (mg) = \left(Impl\ Cath\ Volume\ (mL) + CAP\ Fluid\ Path\ Volume\ (mL)\right) * Old\ Concentration\ \left(\frac{mg}{mL}\right)$	*Assuming Impl Cath Length = 60 cm, Old Concentration = 8 mg/mL* $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156mL$ $Manual\ Bolus = (0.156\ mL + 0.259\ mL) * 8\frac{mg}{mL} = 3.32mg$
Change Drug Conc.	**Changing Drug Conc. (without aspiration)**				
	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.	$CF = \frac{3mL}{Refill\ Volume\ (mL)}$ $Refill\ Syringe\ Concentration\ \left(\frac{mg}{mL}\right) = \left(New\ Concentration\ \left(\frac{mg}{mL}\right) - Old\ Concentration\ \left(\frac{mg}{mL}\right)\right) * CF + New\ Concentration\ \left(\frac{mg}{mL}\right)$	*Assuming Refill Volume = 20mL, New Concentration = 12 mg/mL, Old Concentration = 8 mg/mL* $Reservoir\ Residual\ Correction\ Factor = \frac{3mL}{20mL} = 0.15$ $Refill\ Syringe\ Concentration\ (mg/mL) = (12\ mg/mL - 8\ mg/mL) * 0.15 + 12\ mg/mL = 12.6mg/mL$
	Bridge Bolus Dose Bridge Bolus Duration	Dose and duration of bridging dose transitioning patient's treatment from old targeted daily rate to new targeted daily rate. This takes into consideration the old drug concentration being cleared from the pump and catheter fluid pathway before the new programmed regimen takes over.	When drug concentrations are changed, use this calculation to determine the dose and duration for programming the Bridge Bolus dose and duration.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\left(\frac{mL}{cm}\right)$ $Bridge\ Dose\ (mg) = \left(Pump\ Path\ Volume\ (mL) + Impl\ Cath\ Volume\ (mL)\right) * New\ Concentration\ (mg/mL)$ $Bridge\ Duration = \left(\frac{\left(Pump\ Path\ Volume\ (mL) + Impl\ Cath\ Volume\ (mL)\right) * Old\ Concentration\ \left(\frac{mg}{mL}\right)}{Old\ Targeted\ Daily\ Rate\ \left(\frac{mg}{day}\right)}\right) * 24\frac{hrs}{day}$	*Assuming New Concentration = 12 mg/mL, Impl Cath Length = 60 cm, Old Concentration = 8 mg/mL, Old Targeted Daily Rate = 6mg/day* $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156mL$ $Bridge\ Dose\ (mg) = \left(0.221\ (mL) + 0.156\ (mL)\right) * 12\ \left(\frac{mg}{mL}\right) = 4.524\ mg$ $Bridge\ Duration = \left(\frac{(0.221\ mL + 0.156\ mL) * 8\ mg/mL}{6\ mg/day}\right) * 24\frac{hrs}{day} = 12.064\ hrs$ $= 12hrs + (0.064\ hrs * 60\ min/hr) \approx 12\ hrs\ and\ 4\ \min\ (when\ rounded\ up)$
C A P	**Changing Drug Conc. (with aspiration)**				
	Catheter Aspiration Volume	A calculation of the volume of infusate that should be pulled from the Catheter Access Port in order to remove 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.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\left(\frac{mL}{cm}\right)$ $Aspirate\ Volume = Impl\ Cath\ Volume\ (mL) + CAP\ Fluid\ Path\ Volume\ (mL)$	*Assuming Impl Cath Length = 60 cm* $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156\ mL$ $Aspirate\ Volume = 0.156\ mL + 0.259\ mL = 0.415\ mL$
	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.	$CF = \frac{3mL}{Refill\ Volume\ (mL)}$ $Refill\ Syringe\ Concentration\ \left(\frac{mg}{mL}\right) = \left(New\ Concentration\ \left(\frac{mg}{mL}\right) - Old\ Concentration\ \left(\frac{mg}{mL}\right)\right) * CF + New\ Concentration\ \left(\frac{mg}{mL}\right)$	*Assuming Refill Volume = 20mL, New Concentration = 12 mg/mL, Old Concentration = 8 mg/mL* $Reservoir\ Residual\ Correction\ Factor = \frac{3mL}{20mL} = 0.15$ $Refill\ Syringe\ Concentration\ (mg/mL) = (12\ mg/mL - 8\ mg/mL) * 0.15 + 12\ mg/mL = 12.6mg/mL$
	Bridge 1 Bolus Bridge 1 Duration	The first bridge bolus rapidly advances drug out to the tip of the catheter.	When drug concentrations are changed with aspiration, use this calculation to determine the dose and duration for programming the first Bridge Bolus and duration.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\left(\frac{mL}{cm}\right)$ $Bridge\ 1\ Dose\ (mg) = \left(Pump\ Stem\ Volume\ (mL) + Impl\ Cath\ Volume(mL)\right) * New\ Concentration\left(\frac{mg}{mL}\right)$ $Bridge\ 1\ Duration(\min) = \left(\frac{Pump\ Stem\ Volume\ (mL) + Impl\ Cath\ Volume(mL)}{Maximum\ Delivery\ Rate\ \left(\frac{mL}{\min}\right)}\right)$	*Assuming Impl Cath Length = 60 cm, New Concentration = 12 mg/mL* $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156mL$ $Bridge\ 1\ Dose\ (mg) = (0.068mL + 0.156\ mL) * 12\left(\frac{mg}{mL}\right) = 2.688\ mg$ $Bridge\ 1\ Duration(min) = \frac{0.068mL + 0.156\ mL}{0.02\ \left(\frac{mL}{min}\right)} = 11.2\ min\ \approx 12\ min\ (when\ rounded\ up)$
	Bridge 2 Bolus Bridge 2 Duration	Dose and duration of bridging dose transitioning patient's treatment from old targeted daily rate to new targeted daily rate when the CAP Fluid Path Volume and Implanted Catheter Volume have been aspirated. This takes into consideration the old drug concentration being cleared from the PDS Volume before the new programmed regimen takes over.	When drug concentrations are changed with aspiration, use this calculation to determine the dose and duration for programming the second Bridge Bolus and duration.	$Impl\ Cath\ Volume\ (mL) = Impl\ Cath\ Length\ (cm) * 0.0026\ mL/cm$ VERIFY: $Impl\ Cath\ Volume\ (mL) + Pump\ Stem\ Volume > Precision\ System\ Volume\ (mL)$ $Bridge\ Dose\ (mg) = Precision\ Dosing\ System\ Volume\ (mL) * New\ Concentration\ (mg/mL)$ $Bridge\ Duration = \left(\frac{Precision\ Dosing\ System\ Volume\ (mL) * Old\ Concentration\ \left(\frac{mg}{mL}\right)}{Old\ Targeted\ Daily\ Rate\ \left(\frac{mg}{day}\right)}\right) * 24hrs/day$	*Assuming Impl Cath Length = 60 cm, New Concentration = 12 mg/mL, Old Concentration = 8 mg/mL, Old Targeted Daily Rate = 6mg/day* $Impl\ Cath\ Volume\ (mL) = 60cm * 0.0026\left(\frac{mL}{cm}\right) = 0.156mL$ VERIFY: $(0.156\ mL + 0.068mL) > 0.153mL$ $(0.224mL) > 0.153mL$ $Bridge\ Dose\ (mg) = 0.153\ (mL) * 12\ \left(\frac{mg}{mL}\right) = 1.836\ mg$ $Bridge\ Duration = \left(\frac{(0.153\ mL) * 8\ mg/mL}{6\ mg/day}\right) * 24\frac{hr}{day} = 4.896\ hrs = 4\ hrs + (0.896\ hrs * 60\ min/hr)$ $\approx 4\ hrs\ and\ 54\ \min(when\ rounded\ up)$