SynchroMed II and Isomed Intrathecal Pump Refill Procedure

Related Standards & Resources:

1. B-00-13-10081 - Intrathecal Pump Implant / OR
2. B-00-13-10049- Intrathecal Analgesia Continuous Administration, Chronic Pain Patient Protocol
3. B-00-13-10048- Baclofen (Intrathecal) Continuous infusion protocol

Skill Level- Specialized:

- Registered Nurses and Physicians who have completed the required education, and provide care in the Providence Health Care Neuromodulation Program.

Need to Know:

- **Patients are kept for observation for a minimum of 30 minutes post-pump refill. There is a risk of a pocket fill with any refill.**
- The pump medication is provided and delivered by Burrard Pharmasave. The prescriptions are faxed to Burrard Pharmasave ahead of time, and the originals mailed after pump refills**.**
- Only preservative free morphine, and baclofen, for intrathecal use is approved by Medtronic for infusion through the SynchroMed II pump. Other medications widely used are fentanyl, HYDROmorphone, bupivacaine and clonidine.
- Morphine and baclofen are stable for 180 days in the Synchromed II pump.
- Other drugs are presumed to be stable for up to 90 days.
- The prescribed medication, concentration and flow rate must be ordered ahead of time by a physician familiar with intrathecal drug therapy.
- A Pain Physician must be on site for the refill.
- The drug is double checked by either two registered nurses or a registered nurse and physician prior to refilling the pump.
- Strict sterile technique must be adhered to (the catheter sits in the intrathecal space).
- If there is a change in the type of medication (reference drug) or if the medication concentration has changed from a higher concentration to a lower concentration, a reservoir rinse using 10 mL preservative free 0.9% normal saline for intrathecal use must be performed **twice** prior to filling the pump with the prescribed medication.
    - Definition: Reference drug = drug which pump flow rate is based
    - The drug concentration will be at approximately 93% if pump is filled without a drug reservoir rinse. Rinsing the pump with 3 mL of the prescribed drug increases drug concentration to 98%. Rinsing the pump with 10 mL of the prescribed drug increases the drug concentration to 99%.
- A difference of 25% of actual residual volume compared to expected residual volume is acceptable. To calculate the flow rate percent error use the following formula:

$$\frac{\text{(expected residual volume in mL – actual residual volume in mL)} \times 100}{\text{(previous refill volume in mL – expected residual volume in mL)}}$$

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- A magnet is NOT required for programming the SynchroMed II pump.

Assessment

- Assess the patient's response to therapy and general medical and neurological condition.
- Assessment should include
  - Current pain level, and pain levels over past week.
  - BP, pulse, resps, O_2 sat
  - new or different sensory symptoms (numbness, tingling, burning, hyperesthesia, hyperalgesia)
  - New, occasional, or intermittent bowel or bladder dysfunction
  - New motor weakness, change in gait or difficulty walking
  - Any neurological symptom or sign that differs from baseline
- Assess system performance by:
  - Comparing the expected pump residual volume with the actual residual volume.
  - Checking for pump alarm activation by checking pump logs

PROCEDURE

Equipment and Supplies

1. Medtronic Refill Kit (check expiry date)
2. 20 or 40 mL prescribed medication (35 mL for Isomed pumps)
3. sterile gloves x 2
4. cleansing agent
5. dressing tray
6. Band-Aid
7. N'Vision programmer (not used with Isomed pump)
8. Hand prep e.g. Microsan Encore

SYNCHROMED PUMP

STEPS	RATIONALE
1. Assess patient's response to therapy.	
2. Explain procedure to patient and/or caregiver.	
3. Gather all supplies	
4. Palpate pump site to determine pump location.	
5. Interrogate pump. a. Turn on the 84840 N'Vision programmer.	It is important to verify previous pump programming, particularly if there is to be a change in medication or medication

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b. Select pump icon to navigate to the pump desktop. c. Select SynchroMed II. The 'patient information' screen automatically appears. d. Place programming head over pump and click on 'interrogate'. Follow prompts. e. Review pump status screen, note the expected reservoir volume, calibration constant, ERI (**E**stimated pump **R**eplacement **I**nterval). Ensure calibration constant value is the same as it was at last refill.	concentration. The residual volume value tells you how much to expect when you aspirate the pump. The information also alerts you to alarms and when pump needs to be replaced.
6. Double check the prescribed medication with another registered nurse or physician.	The medication is concentrated and is delivered to the intrathecal space.
7. Using aseptic technique, open refill kit and prepare supplies for refill.	
8. Use hand prep and put on sterile gloves.	
9. Maintaining aseptic technique, prepare injection site using a swab with cleansing agent spread in a circular motion from the centre outward, beyond the periphery of the pump. Repeat this procedure x 3. Allow cleansing agent to dry.	
10. Remove and discard gloves and prep materials. Wash hands or use hand prep.	
11. Put on next set of sterile gloves and assemble 20 mL sterile syringe, extension tubing and 22 gauge non-coring needle from refill kit. Ensure clamp on extension tubing is closed.	Clamp to prevent air from entering the system.
12. Place sterile fenestrated drape over patient, exposing pump site.	
13. Centre the template over the pump. Locate the reservoir fill port septum at the centre of the template by lining up landmarks of pump (catheter access port and pump margins)	
14. Insert needle into reservoir fill port septum at a 90 degree angle until you feel the needle touch the metal needle stop.	This ensures that the needle is firmly in position, and minimizes the risk of the drug entering subcutaneous tissue.
15. Open clamp on extension tubing. You should see clear fluid (medication) begin to empty into syringe.	

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16. Maintaining negative pressure at all times, aspirate contents from pump until air bubbles are observed in the syringe**. DO NOT ALLOW AIR TO ENTER PUMP. DO NOT DISCARD FLUID WITHOUT MEASURING.** 	Air in the system can activate the reservoir valve, and it will not be possible to fill the pump. If this happens; empty the pump and start over.
17. Once all residual volume has been removed from pump, clamp extension tubing and place syringe in sterile field while still attached.	
18. If decreasing drug concentration or changing medication, rinse the reservoir with 10 mL **preservative free** sterile 0.9% normal saline twice using the refill and emptying procedures outlined in this procedure (Make sure to use a 0.22 micron filter)	A small amount of medication remains in the pump reservoir.
19. Attach the 0.22-micron bacteria retentive filter to the 20 mL syringe with prescribed medication and flush to distal tip of filter.	Flushing purges air from system.
20. Attach the primed filter and syringe containing the medication to extension tubing.	
21. Open clamp and slowly inject medication into pump at a rate of no faster than 1 mL/3 seconds. Every few mL aspirate to ensure that your needle is still firmly secured in the pump reservoir.	Attempting to fill faster or exceeding pump reservoir capacity may result in activation of the reservoir valve. Note: If the valve is activated before the pump is filled completely, discontinue injection, clamp tubing and remove

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	needle from reservoir port. Return to "emptying the pump".
22. Close the clamp on the extension tubing and remove the needle from the reservoir fill port.	
23. Apply firm pressure to injection site with gauze and apply an adhesive bandage.	
24. Measure and compare actual residual volume to expected residual volume.	A significant discrepancy could indicate pump failure, or a problem with the catheter. See calculation formula
25. Program pump as follows: a. Exit out of screen by clicking small x in right hand corner. The patient information screen will be displayed. b. Select **INFUSION DRUG ICON** – review drug name, concentration, dosing units and reservoir volume. Make changes according to physician orders. Follow prompts. Confirm the volume of the prescribed medication does not exceed the reservoir capacity of the pump and enter this amount into the reservoir volume box. c. Select **INFUSION MODE ICON** – review infusion mode, doses/day and make changes according to physician orders. d. Select **INFUSION BOLUS ICON** – if a drug concentration change or drug solution change has been made you must program in a bridge bolus. The programmer will automatically default to a bridge bolus if a change in solution or drug concentration has been made. The pump tubing and catheter volume will automatically be displayed, as will the bolus dose. Enter the old drug desired dose. The bolus duration is automatically calculated and can not be altered. e. Select **ALARMS ICON** – review screen noting ERI and reservoir volume. Enter low reservoir alarm volume at no less than 1 mL. Ensure that the refill interval is no greater than the drug stability or 180 days, which ever is less. Set critical alarm at 10 minutes, and non-critical alarm at 1 hour.	

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f. Select **SUMMARY ICON** – Review the new pump settings with another RN prior to updating the pump. Place programming head over pump and select update pump. Follow prompts. Ensure you maintain telemetry with pump during update and verify phase. Once telemetry complete select OK. Exit out of screen before printing by clicking on small x of screen g. **Select printer** icon at top of the screen and select both new and current pump settings. Select drop down screen from top left hand corned or programmer. Click on printer picture again. A list of reports will appear. The patient report you just sent will have *P beside it, indicating it is waiting to print. Ensure it is highlighted. Click on the print icon on the far left for a short report or the middle icon for a long report. Line up the N'Vision programmer's infrared port 30 cm from the infrared port on the Medtronic Dongle in Office Computer h. Exit out of program once printing complete	
26. Provide a copy of the programming print out for the patient. Review information with patient.	
27. Confirm refill date.	
28. Complete all documentation required for patients chart.	

ISOMED PUMP

STEPS	RATIONALE
1. Assess patient's response to therapy.	
2. Explain procedure to patient and/or caregiver.	
3. Gather all supplies and check expiry dates.	
4. Calculate the expected residual volume. 5. [Previous refill volume- (flow rate in mL/day x number of days since last refill)]	The residual volume value tells you how much to expect when you empty the pump.

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6. Double check the prescribed medication with another registered nurse or physician.	The medication is concentrated and is delivered to the intrathecal space. – See IDG1117 Independent Double Check and Double Check of Medication
7. Palpate pump site to determine pump location, and centre fill port.	
8. Using aseptic technique, open refill kit and prepare supplies for refill.	
9. Use hand prep and put on sterile gloves.	
10. Maintaining aseptic technique, prepare injection site using a swab with cleansing agent spread in a circular motion from the centre outward, beyond the periphery of the pump. Repeat this procedure x 3. Allow cleansing agent to dry.	
11. Remove and discard gloves and prep materials.	
12. Use hand prep and put on next set of sterile gloves and assemble 20 mL sterile syringe, extension tubing and 22 gauge non-coring needle from refill kit. Ensure clamp on extension tubing is closed.	To prevent air from entering the system.
13. Place sterile fenestrated drape over patient, exposing pump site.	
14. Centre the template over the pump. Locate the reservoir fill port septum at the centre of the template.	To avoid a pocket fill.
15. Insert needle into reservoir fill port septum at a 90 degree angle until you feel the needle touch the metal needle stop.	This ensures that the needle is firmly in position, and minimizes the risk of the drug entering subcutaneous tissue.
16. Open clamp on extension tubing. You should see fluid begin to empty into syringe. **Do not aspirate** when emptying the pump. When backflow has stopped, wait approximately 5 seconds to ensure that all the fluid is removed and the pump is empty.	Fluid from the reservoir will flow into the syringe until the pump is empty. Aspiration can damage the pump. **Caution:** Failure to withdraw all of the residual drug from the pump reservoir and then overfilling the reservoir can lead to overpressurization. Overpressurization can result in clinically significant drug overdose or cause damage to the pump.
17. **DO NOT allow air to enter pump.**	

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18. Once all residual volume has been removed from pump, clamp extension tubing and place syringe in sterile field while still attached.	
Refilling the Pump 19. Due to the amount of pressure required to fill the pump, have the medication prepared in 10 mL syringes.	
20. If decreasing drug concentration or changing medication, rinse the reservoir with 10 mL **preservative free** sterile 0.9% normal saline twice using the refill and emptying procedures outlined in this procedure.	A small amount of medication remains in the pump reservoir.
21. Attach the 0.22-micron bacteria retentive filter to the syringe with prescribed medication and flush to distal tip of filter.	
22. Attach the syringe and filter to the extension tubing	
23. Open clamp and slowly inject medication into pump.	**Note**: A considerable amount of pressure is required to inject fluid into the pump reservoir.
24. Close the clamp on the extension tubing and remove the needle from the reservoir fill port.	
25. Measure and compare actual residual volume to expected residual volume.	A significant discrepancy could indicate pump failure, or a problem with the catheter. See calculation formula in "need to know" section.
26. Apply firm pressure to injection site with gauze and apply an adhesive bandage.	
27. Calculate refill date. Do not allow the fluid volume in the reservoir to fall below 2 mL.	If the fluid volume in the reservoir is less than 2 mL the pump output will decrease significantly (more than 25%) Refill interval in days = [Reservoir fill volume minus 2 mL] x pump flow rate
28. Complete all documentation required for patients chart.	

Patient Education:

- Signs and symptoms of overdose or withdrawal from pump medications.
- Book a follow-up appointment prior to discharge.
- Provide them with the emergency Neuromodulation pager number.

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- Provide patients with a print-out of their pump medications
- For Synchromed pumps, review pump alarms, the significance of the alarms, and demonstrate the sound of the alarms
- Synchromed pumps must be checked following an MRI. Strong magnets temporarily stop the pump motor and the pump may need to be reprogrammed. MRI appointments need to be coordinated with the pump nurse.
- Not to use a hot tub, steam room, sauna or tanning bed where temperature is greater than 39 degrees C. At higher temperatures the pressure in the pump increases and may cause the pump to deliver too much medication.

Patient Resources:

- Medtronic Synchromed 11 patient booklet.
- Post-Op discharge Instructions for Intrathecal Pump.
- Medtronic Pocket Information cards for morphine and/or baclofen emergency information.

Documentation

- The pump medications, including: amount, concentration, priming dose, daily dose.
- Amount of medication expected residual volume and actual residual volume.
- Pain assessment, vital signs
- Assessment of the patient's general condition and response to therapy.
- Print-out of pump program (from Medtronic N'Vision programmer).
- Follow-up appointment.
- List of medications

References:

1. Deer, T. et al. (2012) Polyanalgesic consensus conference 2012: Recommendations for the management of pain by intrathecal (intraspinal) drug delivery: Report of an interdisciplinary expert panel. Neuromodulation: Technology at the Interface 15, (5) 436-466.
2. Deer, T. et al. (2012) Polyanalgesic consensus conference 2012: Recommendations to reduce morbidity and mortality intrathecal drug delivery in the treatment of chronic pain. Neuromodulation: Technology at the Interface 15, (5) 467-482.
3. Deer, T. et al. (2012) Polyanalgesic consensus conference 2012: Consensus on diagnosis, detection, and treatment of catheter-tip granulomas (inflammatory masse) Neuromodulation: Technology at the Interface 15, (5) 483-496.
4. Deer, T.; Krames, E; et al (2008). Neuromodulation: technology at the neural interface.11(2), 92-97, International Neuromodulation Society publication.
5. Hawley, P., Beddard-Huber, E., Grose, C., McDonald, W., Lobb, D., & Malysh, L. (2009).Intrathecal infusions for intractable cancer pain: A qualitative study of the impact on a case series of patients and caregivers. Pain Research and Management, 14 (5), 371-379.
6. Hocking, G. & Wildsmith, J.A. (2004). Intrathecal drug spread. British Journal of Anaesthesia, 93 (4), 568-78.

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7. Kalso, E. (2005). Pharmacological management of pain: anticonvulsants, antidepressants and adjuvant analgesics. In Pain 2005—an updated review: refresher course syllabus, Justin,D.M. (ed), Seattle, WA: IASP press, 19—29.
8. Maneyapanda, M,, Chien, G, Mattie, R., Amorapanth, P., Reger, C & McCormick Z. (2016). Ultrasound guidance for technically challenging intrathecal baclofen pump refill. American Journal Physical Medicine Rehabilitation, 95 (9), 692-697.
9. McCaffery, M. & Pasero, C. (2011). Intraspinal analgesia in Pain Assessment and Pharmacological Management, St. Louis, Missouri, Mosby Inc.
10. Textor L. (2016). Intrathecal pumps for managing cancer pain: What every nurse should know about these programmable medication delivery systems. *American Journal of Nursing 116 (5*). 36-44.
11. Turner, M.S (2003) Intrathecal drug delivery. Acta Neurochirurgica Supplementum, 87: 29-35.
12. www.medtronic.com (2012).
13. Medtronic 2004, Programming in ' in SynchroMed® II programmable infusion system clinical reference guide, Medtronic, Inc., Minneapolis, MN. 2009 Pump Implant OR Procedure
14. Medtronic 2009 Synchromed 11 Programmable Pumps Implant manual.
15. Medtronic Information for prescribers. Medtronic (2010).
16. Roberts, J. (2016). Troubleshooting intrathecal drug delivery systems. Emergency Medicine News. 10-12.

Persons/ Groups Consulted

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