SUBJECT: Patient controlled analgesia (PCA) and opioid infusions by intravenous or subcutaneous route - Adult/Pediatric

DEPARTMENTS: Nursing

PURPOSE:
To outline the nursing management of patients receiving intravenous or subcutaneous opioid infusions using the PCA pump.

POLICY:
1. The PCA pump is a locked drug delivery system that is used to provide self-administration of opioids by the patient. The PCA pump can be programmed as PCA with or without a continuous opioid infusion (Basal rate).
2. PCA opioid concentrations are standardized. Exceptions to the opioid concentration and/or delivery device can be considered on a case-by-case basis. A lock-box will be used for opioid infusions when the PCA pump is not used.
3. Only RNs can operate the PCA pump or deliver a bolus dose using the PCA pump to the patient per Licensed Independent Provider (LIP) orders.
4. End Tidal CO2 (EtCO2) monitoring shall be implemented on all patients requiring PCA treatment or opioid infusion for the duration of the therapy. Exceptions are:
   a. Patients requiring end of life or comfort care.
5. Patients who are on mechanical ventilation will have EtCO2 monitoring via an inline monitor.

PROCEDURE:
A. PATIENT SELECTION:
1. Patient candidates for use of the PCA self-dosing option are the following:
   a. Patients who are mentally alert to understand and comply with instruction and are physically able to press the PCA dosing button.
   b. Patients with no history of allergies or severe side effects to prescribed opiate.
   c. Pediatric patients age 8 years old and above who demonstrate the ability to understand PCA concepts and operate the device. The child's developmental level, cognitive level, and motor skills should also be considered.
2. When a patient cannot properly use the PCA button or comply with instructions because of physical, mental or emotional factors, contact the physician to discontinue the PCA patient dosing.
3. Closely monitor patients who are at risk for opioid-induced respiratory depression. Patients may have one or more of the following to be considered high risk:
   a. Sleep apnea or sleep disorder diagnosis.
   b. Morbid obesity with high risk of sleep apnea.
   c. Snoring
   d. Older age: Greater than 60 years old.
   e. No recent opioid use.
   f. Post-surgery, particularly if upper abdominal or thoracic surgery.
   g. Increased opioid dose requirement.
   h. Longer length of time receiving general anesthesia during surgery.
   i. Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants.
   j. Preexisting pulmonary or cardiac disease or dysfunction or major organ failure.
   k. Thoracic or other surgical incisions that may impair breathing.
   l. Smoker

B. PCA ORDERS:
1. A complete PCA orders must be reordered with any prescription change, and must have the following components as indicated:
a. Name of the drug & concentration.
b. Loading dose.
c. PCA or patient bolus dose.
d. Lock-out or bolus interval.
e. One hour limit dose.
f. Basal rate (if on continuous infusion).

2. The PCA orders must be reviewed, approved and verified by a pharmacist prior to initiating the infusion.

3. Pediatric orders must be written as weight based.

C. PCA VERIFICATION:
   1. The pump is programmed by dosage not volume i.e. **milligrams or micrograms not milliliters (mL)**.
   2. **Two RNs** must review and sign for the correct settings on the PCA device when:
      a. Changes are made to dose or rate (programming, reprogramming) or changing medication syringes/IV tubings.
      b. During shift hand-off, and patient transfer (between units) or change in level of care.
      c. Two nurse verification, and sign on in the PCA section of the electronic medical record:
         i. The total PCA dose infused during the shift.
         ii. Number of patient attempts to press the button.
         iii. Number of actual dose or injections delivered by the pump.
         iv. Amount of remaining opioid drug in the syringe (reserve volume).
         v. Clear the pump history at the end of each shift.

3. **PCA Boluses**: Initial PCA boluses should be done through the PCA and witnessed by a second RN.
   a. Subsequent boluses should be dispensed from the Omnicell and do not require a second RN witness.

4. **If PCA is discontinued**, record the amount of remaining medication, and waste remaining medication according to controlled substance policy.

D. PCA Set-up and programming
   1. **PCA IV set up**
      a. Attach the PCA medication syringe to the infusion tubing and prime.
      b. Attach a primed IV fluid tube to the Y connector of the PCA pump tubing. Use a special anti-reflux connector to the IV tubing so that no opioid can reflux into the primary IV tubing. Reflux tubing is not needed for a subcutaneous infusion.
      c. Obtain physician order for "to keep open" (TKO) IV to run with the PCA. A TKO IV is not required for a subcutaneous infusion.
      d. Confirm that the instructions sign **"No Proxy Dosing"** is posted on the IV pole.
      e. The PCA medication syringe is changed **every** 24 hours and the tubing **every** 96 hours.

   2. **Pump programming**
      a. Obtain PCA module and follow manufacturer's guidelines in pump set up and programming.
      b. Program the PCA module to deliver the prescribed medication dose (basal and on-demand), lockout interval, and maximal dose. Follow verification process with another RN.
      c. Connect the PCA pump IV tubing to the patient's IV access port after priming & secure.
      d. Trace IV lines from patient to device. Avoid forcing connections to prevent misconnection of IV lines.
      e. Have the patient demonstrate use of the PCA system.

3. **PCA Pause Protocol**
   a. The PCA infusion will automatically pause and PCA patient dose cord become inactive when the patient's respiration fall below the established alarm configuration (RRiess than 6/min).
   b. An alarm and screen message on the module will alert the staff that the PCA has paused.
   c. The RN shall assess the patient, troubleshoot, adjust dose or alarm parameters, and restart or discontinues the PCA based on patient's clinical status and or upon orders of the UP.
   d. The RN may adjust the RR alarm settings within hospital's default settings as clinically appropriate.

E. End Tidal C02 (EtC02) Monitoring
1. Patients on PCA should be on EtC02 monitoring continuously. The RN may suspend monitoring when patient is eating, taking a shower, or ambulating. Resume monitoring when activity is complete.
2. If possible, determine the patient's baseline ETC02 value, trend, and waveform before initiating PCA for comparison.
3. Set up the ETC02 monitoring system per the manufacturer's instructions:
   a. Obtain ETC02 module and C02 monitoring line (a single-piece airway gas sampling lines comprised of the patient cannula, moisture trap and a filter).
   b. Set up the ETC02 module, connect and apply the C02 monitoring line to patient according to manufacturer's instructions.
   c. Oxygen supplement is not required for EtCo2 monitoring unless clinically indicated or ordered.
   d. If a patient requires oxygen, it may be delivered through C02 monitoring line up to a maximum of 5 L/minute. Any additional oxygen required will have to be given through additional tubing or mask.
   e. In patients requiring BiPap/Continuous Positive Airway Pressure (CPAP), a full face mask should be used during ETC02 monitoring.
4. Module default ETC02 alarms settings.

<table>
<thead>
<tr>
<th>Population</th>
<th>Parameter</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>ETC02</td>
<td>60 mmHg</td>
<td>15 mmHg</td>
</tr>
<tr>
<td></td>
<td>Respiratory rate</td>
<td>40 bpm</td>
<td>6 bpm</td>
</tr>
<tr>
<td></td>
<td>Apnea</td>
<td>20 seconds</td>
<td></td>
</tr>
<tr>
<td>Pediatric (greater or equal to 8 years old)</td>
<td>ETC02</td>
<td>50 mmHg</td>
<td>15 mmHg</td>
</tr>
<tr>
<td></td>
<td>Respiratory rate</td>
<td>60 bpm</td>
<td>10 bpm</td>
</tr>
<tr>
<td></td>
<td>Apnea</td>
<td>15 seconds</td>
<td></td>
</tr>
</tbody>
</table>

a. ETC02 alarm limits may be modified from the default parameters according to patient condition or as medically necessary (for example, patient is a C02 retainer):
   1. The assigned RN will notify the LIP of the abnormal alarm findings or patient condition. The LIP will write an order to change the ETC02 monitor limits.
   2. The RN will call the Respiratory Care Practitioner (RCP) assigned to the floor to change the alarm settings on the ETC02 module.
   3. The RN and RCP will document actions, findings and new alarm parameters in the electronic health record.

b. When checking ETC02 levels observe and correlate capnograph waveform for validity and accuracy.

5. ETC02 Alarms:

<table>
<thead>
<tr>
<th>High Priority Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>No breath detected</td>
<td>No breath has been detected for a specified period of time.</td>
<td>Assess patient, Check connections and disposable line.</td>
</tr>
<tr>
<td>Low RR</td>
<td>Respiratory Rate is below the specified limit.</td>
<td>Assess patient condition and confirm alarm limit values.</td>
</tr>
<tr>
<td>High RR</td>
<td>Respiratory Rate is above the specified limit.</td>
<td>Assess patient condition and confirm alarm limit values.</td>
</tr>
<tr>
<td>High EtCo2</td>
<td>EtCo2 is above the</td>
<td>Assess patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Possible Clinical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>May indicate patient is apneic or C02 monitoring line may have been disconnected. Intervene per PCA orders or activate emergency response if apnea occurs with unresponsiveness to stimulation.</td>
</tr>
<tr>
<td>Low respiratory rate may indicate over sedation. Stimulate patient, check responsiveness, reduce opioid dose, administer reversal agent or initiate emergency measures as indicated.</td>
</tr>
<tr>
<td>May indicate respiratory difficulty or inadequate pain control. Assess cause of tachypnea and intervene as indicated.</td>
</tr>
<tr>
<td>Increase in ETC02 10% from baseline, or 50</td>
</tr>
</tbody>
</table>

Table 1. Default Settings of ETC02

Table 2. ETC02 Alarm Scenarios
specified limit. condition and confirm alarm limit values. mm Hg or greater in patients who are not identified as C02 retainer may indicate hypoventilation or decreased respiratory rate. Assess patient and notify LIP of EtCO2 trends to determine need to adjust PCA dose.

<table>
<thead>
<tr>
<th>Low EtCO2</th>
<th>EtCO2 value is below the specified limit.</th>
<th>Assess patient condition and confirm alarm limit values.</th>
<th>Decrease in EtCO2 may indicate hyperventilation or respiratory depression with low tidal volumes. Investigate cause of hyperventilation. Implement respiratory support as clinically indicated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disconnect Occluded Disposable</td>
<td>Purging operation failed.</td>
<td>Check CO2 monitoring line, change as indicated.</td>
<td>Change filter as required. Excessive secretions or buildup of condensation in the airway tubing may occlude sampling line, attempt to disconnect and then reattach. If still problematic, tubina may need to be chananed.</td>
</tr>
</tbody>
</table>

a. Sedation precedes respiratory depression. Assess trends in sedation level and EtCO2 levels, and evaluate if sedation is a result of the opioid, other sedating medication, or the patient's clinical condition. Notify LIP to adjust medication if sedation persists or increases.

b. Consult RCP to assist in assessing patient's respiratory status, EtCO2 trends interpretation, and troubleshooting alarms.

**PATIENT ASSESSMENT & MONITORING**

A. For adult patients:
   1. Assess the patient's cognitive ability to comply with PCA treatment.
   2. Assess, monitor, and document the following (Table 3)

<table>
<thead>
<tr>
<th>Situation</th>
<th>Frequency</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before initiating PCA</td>
<td>Baseline before PCA initiation</td>
<td>a. Vital signs (blood pressure, pulse rate, respiratory rate, and pulse oximetry (SP02)</td>
</tr>
<tr>
<td>After initiating PCA, changing type of medication used, administering bolus, or increasing dose.</td>
<td>Recheck within 30 minutes*.</td>
<td>b. Continuous EtCO2 levels</td>
</tr>
<tr>
<td>Routine monitoring for the entire duration of PCA therapy</td>
<td>Every 4 hours*</td>
<td>c. Pasero Opioid-Induced Sedation Scale (POSS)</td>
</tr>
<tr>
<td>Post procedure or post-operative patients.</td>
<td>Per post op orders or whichever is more frequent*</td>
<td>d. Pain levels</td>
</tr>
<tr>
<td>Comfort care</td>
<td></td>
<td>Follow specific physician orders for monitoring frequency, whichever is more frequent</td>
</tr>
</tbody>
</table>

3. Assess the adequacy of pain control by reviewing PCA settings, especially number of “attempts” and “injections” in relationship to the pain rating. If pain level is high, contact physician to evaluate need to increase PCA dose or basal rate.

B. For pediatric patients:
   1. Upon initiation of a PCA, all pediatric patients must be placed on concentrated care for a minimum of 24 hours.
   2. Pediatric orders must be written as weight based.
   3. Instruct family members not to push the button for the child.
4. Assess, monitor, and document the following:
   a. **Within 15 minutes** following initiation of PCA therapy, following a bolus injection, or following any change in rate, dose or concentration:
      1. Respiratory and pulse oximetry levels (Sp02).
      2. Continuous EtC02
      3. Sedation level
      4. Pain level using age appropriate tool.
      5. Side effects noted.
   b. **Every 1 hour for the first 4 hours** of PCA therapy and then **every 2 hours** for the duration of PCA therapy:
      1. Respiratory and Sp02.
      2. Continuous EtC02 levels
      3. Sedation level
      4. Pain level using age appropriate tool.
      5. Side effects noted.
      6. Total dose infused.

C. Side effect interventions
   1. Unexpected over sedation/respiratory depression.
   2. Respiratory depression:
      a. Adults: respirations shallow and less than 10 bpm.
      b. Pediatric patients:
         1) 8-10 yrs: less than 16 bpm
         2) 11-18 yrs: less than 12 bpm
   3. Oxygen saturation less than 90%.
   4. Somnolence with Pasero Opioid-induced Sedation Scale (POSS) of 3 and above. Pasero Opioid-Induced Sedation Scale (POSS) Procedure
   5. Take the following actions:
      a. Stop PCA and other potentially sedating medications.
      b. Maintain IV access.
      c. Stimulate patient and encourage deep breaths.
      d. Obtain vital signs.
      e. Verify correct programming and total PCA dose infused since last checked.
      f. Administer Naloxone (Narcan) per order if respiratory depression persists.
      g. Notify physician managing PCA STAT. Obtain orders to decrease opioid dose and/or other sedating medications.
      h. Monitor vital signs frequently as clinically indicated and continue EtCo2 monitoring. In patients who remain unstable, notify provider and consider patient transfer to higher level of care for close monitoring.
      i. If side effects occur, access respiratory rate, oxygen saturation, pain score and sedation level every hour for 12 hours.
   6. For mental status changes such as sedation, confusion and agitation:
      a. Assess for other possible cause of mental status change (i.e. stroke, hypoglycemia)
      b. Provide a safe environment.
      c. Implement fall prevention bundle.
   7. Nausea/vomiting- obtain order for antiemetic. Consider need for around the clock scheduled dosing.
   8. Constipation -monitor bowel function and assess need for scheduled stool softeners/stimulants and laxatives.
   9. Dry mouth- provide frequent mouth care.
   10. Urinary Retention - obtain LIP order for catheterization as needed.
   11. Pruritus- obtain order for treatment with antihistamines or antipruritic medications.
   12. Myoclonus and seizures may occur with chronic high dose opioid administration - evaluate potential use of a benzodiazepine to control symptom with LIP.

REPORTABLE CONDITIONS:
1. No proxy PCA dosing (activation of PCA button by anyone but the patient) is permitted. A sign shall be placed on each PCA pump stating that only the patient can activate the PCA button. The nurse will contact the physician to discontinue PCA dosing if this policy is consistently violated.

SAFETY
A. Keep the following at the bedside:
   1. 02 set up with NC.
   2. Complete suction set-up.
B. Have the following readily available:
   1. Ambu bag—appropriate size for age.
   2. Naloxone (Narcan)
C. Keep PCA device locked on an IV pole when in use.
D. Maintain sign: no proxy dosing on the pump at all times.
E. Keep PCA keys secure. DO NOT leave keys unattended.

TEACHING:
A. Teach the patient and family why PCA is being used and how and when the patient should use it.
   1. Discuss with patient to push the button whenever he or she feels pain is starting.
   2. Instruct the patient regarding the potential side effects of the medication.
   3. Instruct patient and parents/family/significant others as appropriate about no proxy PCA dosing (only the patient is allowed to push the button). Discuss with patient/family that overdose may occur if no proxy PCA policy is not strictly followed.
B. Instruct patient to report potential side effects including: difficulty breathing, itching, nausea/vomiting, dizziness, lethargy or urinary retention and inadequate pain relief.
C. Explain the purpose of the EtC02 monitoring.
D. Inform the patient of nonpharmacological pain-management strategies that may supplement or enhance pharmacologic intervention.
E. Provide "Managing your pain with Patient Controlled Analgesia" patient education handout.

DOCUMENTATION:
A. Document vital signs, Sp02, EtC02 levels, sedation scores (POSS), pain assessment and pain control using the age and condition appropriate tools in Electronic Medical Record (EMR).
B. Document medication administration and verification performed by two RNs:
   1. PCA Prescription: Drug, concentration, dose, and frequency.
   2. Bolus doses given.
   3. Date discontinued, volume remaining/wasted, RN signature/nurse co-signature.
   4. Total PCA dose in "mg" administered during the shift
   5. Assessment parameters as indicated.
C. Document in the interdisciplinary education patient and family education related to PCA use.
D. Document side effects and adverse responses or adverse change in patient condition in EMR.
E. Patient/family response to teaching.

DEFINITIONS:
Patient-controlled analgesia (PCA) is a method of pain management that gives the patient control over pain through self-administration of analgesics. PCA pump refers to the device used to deliver the analgesic.

A PCA pump is a type of infusion pump consisting of an infusion device, a prefilled medication reservoir, and tubing that delivers the medication from the infuser through the patient-control module to tubing connected to IV fluid, which runs at a continuous rate. PCA pumps are individually programmed to deliver automatically a specific practitioner-prescribed continuous infusion (basal rate) of medication, a bolus dose (patient initiated), or both.

PCA Prescription — written by LIP giving the parameters for the pump programming.
Dose (Patient Controlled)- amount of medication per injection received when the PCA button is pressed by the patient.

Delay (Dose Interval Lockout)- period of time between doses in which the PCA button cannot be activated to administer PCA dose.

Basal Rate- continuous infusion rate of the opioid.

One Hour Limit (Dose limit)- maximum amount of opioid that can be delivered over one hour.

Bolus Dose- (Use "Loading Dose" Pad) - medication given on a prn basis by RN or LIP.

REFERENCES:

ASSOCIATED POLICIES:
Controlled Substance Documentation / Non-Automated
Medication Management: High Risk Medications
Management of Controlled Substances

ORIGINATED:
7/10/09

LAST APPROVALS:
MSJMC Medical Executive Committee, MSJMC Operations Committee, MSJMC Pediatrics Committee,
MSJMC Pharmacy/Therapeutics/Infection Control, MSJMC Policy & Procedure Committee, MSJMC
Surgery Committee, SSA Community Board

APPROVED:
01/27/2017
FilterLine® is the patented family of innovative, single-patient etCO\textsubscript{2} breath sampling lines for Microstream® Capnography enabled monitors and for use with non-intubated or intubated patients.

A full array of FilterLine patient sampling lines is available to meet every patient and clinical need, featuring oral and nasal sampling as well as an innovative supplemental O\textsubscript{2} delivery system.

**FEATURES**
- One size fits adolescents through adults
- Single patient use
- Latex free
- Can be used with bi-level ventilation and CPAP
- Short- and long-term options available

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A full array of FilterLine patient sampling lines is available to meet every patient and clinical need, featuring oral and nasal sampling as well as an innovative supplemental O\textsubscript{2} delivery system.

**SMART FILTERLINE® H PLUS**

**Uni-junction™** – Patented design permits upward or downward pressure of the breath at the junction, allowing only that source of breath (with the greatest pressure) to be sampled.

**Filter** – Sterilizing grade hydrophobic filter material with a 0.2 micron pore size allows patient breath to pass through the hollow structure while reducing risk of biohazard contamination of the monitor.

**Oral scoop** – Designed to provide quality etCO\textsubscript{2} samples when the patient is mouth breathing. Surface area design provides sampling accuracy in the presence of low tidal volumes.

**O\textsubscript{2} delivery** – Flows from holes in front of nasal prongs and improves humidity of O\textsubscript{2}. Delivers flow up to 5 L/min and can deliver above 5 L/min using external O\textsubscript{2} delivery, (i.e. CPAP).

**Microbore tubing** – Small, 1.0 mm internal diameter sampling line designed to facilitate faster response time.
SMART FILTERLINE® H PLUS

0.2 micron Filter
Sterilizing grade filter designed to reduce risk of biohazard contamination of the monitor

Oral Scoop
Provides accurate sampling for mouth breathers

Uni-junction™
Enables etCO₂ sampling from either the nares or the mouth

Dual nare sampling
Designed to ensure proper sampling from either nare

Tubing for O₂ delivery
(May be used with or without oxygen delivery)
O₂ delivery from holes in front of nasal prongs

Connector compatibility
Connects to all Microstream® enabled products

Nafion®* for long term monitoring
(Or alternate moisture reduction technology)

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QUICK REFERENCE GUIDE

Operator Precautions:
To ensure proper operation of the Alaris® System (formerly known as "Medley® System"), user must be familiar with related features, disposables, administration sets, set-up and programming.

This guide is not intended to be comprehensive instructions for the setup and operation of the Alaris System. For complete instructions along with Warnings and Cautions, refer to Alaris System Directions for Use (v8).

Syringe Loading and Set-Up

Loading:
1. Open syringe barrel clamp (clear piece) until it clears syringe chamber.
2. Raise drive head (gray) to fully extended position.
3. Insert syringe barrel flange between barrel flange grippers.
4. Lock syringe in place by closing barrel clamp.
5. Twist gripper control clockwise, lower drive head, lock plunger in place with plunger grippers.

Removal:
1. Close tubing clamp.
2. Unlock door with key, open plunger grippers and syringe barrel clamp. (Silence safety alarm).
3. Remove syringe.

Note: At the start of an infusion program, the system prompts to select and confirm syringe type and size. Ensure displayed syringe manufacturer and size correctly identifies the installed syringe.

Priming:
1. Select administration set and attach set to syringe.
2. If priming manually, express air from administration tubing set.
3. If priming using Alaris® PCA Module (PCA Module), this feature is available when viewing Infusion Mode screen during programming of PCA Module. At this screen Press OPTIONS, then press PRIME SET WITH SYRINGE.

4. Once tubing set is primed, close slide clamp.

Detaching Module:
Use key to unlock door. Inside locate lever and depress. At the same time holding the module and moving the bottom of the module sideways and away from Alaris® PC Point-of-Care Unit (PC Unit).

WARNING
To prevent uncontrolled flow, close set tubing clamp before loading or unloading syringe.
Programming an infusion using Guardrails®Suite MX Protection

Initial Set-Up:
1. Load syringe with administration set attached.
2. Press SYSTEM ON key.
3. Select YES or NO to "New Patient".
4. Select appropriate profile.
5. Press CHANNEL SELECT key.
6. Set key to Program position.
7. Press CONFIRM time setting.
8. Choose correct syringe type and size. (If syringe selection is not displayed press ALL SYRINGES)
9. Choose correct medication and concentration.
10. Respond to appropriate clinical advisory.
11. Review monitoring alarm limits (if applicable).
12. At "Infusion Mode" screen: To Prime, press OPTIONS key.
13. Press PRIME SET WITH SYRINGE.
14. Press and hold PRIME key to prime tubing.

**WARNING**
Do not prime while attached to patient.
15. Press EXIT when prime is complete.
16. Choose desired Infusion Mode and follow on-screen prompts.
17. Close and lock door.
18. Attach administration set tubing set to patient.
19. Review settings and press START.

Change Syringe:
1. Press PAUSE.
2. Close tubing clamp.
3. Use key and unlock door.
4. Remove old syringe.
5. Press SILENCE.
6. Attach new syringe to tubing.
7. Load new syringe.
8. Set key to Program position, close door.
9. Press CHANNEL SELECT.
10. Choose correct syringe type and size. (If syringe selection is not displayed press ALL SYRINGES)
11. Press CONFIRM.
12. Press RESTORE if same drug and concentration.
15. Lock door and open tubing clamp.
16. Review settings and press START.

Change Program/Mode:
1. Press CHANNEL SELECT key.
2. Press PROGRAM.
3. Set key to "Program" position or enter authorization code (if enabled).
4. Press CHANGE MODE soft key.
5. Choose desired infusion mode and follow onscreen prompts.

Reviewing or Changing PCA Pause Alarm Limits:
1. Press CHANNEL SELECT key.
2. Press OPTIONS key.
3. Select PCA Pause Limits.
4. Review change limits per hospital protocol.
5. Press CONFIRM and START.

**Note:** This function requires use of monitoring module(s).

Disabling PCA Pause Alarm:
1. Press CHANNEL SELECT key.
2. Press OPTIONS key.
3. Select PCA Pause Limits.
5. Press CONFIRM and START.
Beginning of Shift/Summary
Review:
1. Press CHANNEL SELECT key.
2. Verify syringe type/size, drug/concentration and settings.
3. Press START key.

Patient History/End of Shift/24hr History
1. Press CHANNEL SELECT key.
2. Press OPTIONS.
3. Press PATIENT HISTORY.
4. Review drug totals.
5. Press ZOOM key (time interval) as appropriate.
6. To clear patient history press CLEAR HISTORY.
7. Press YES or NO.
8. To view 24 hour totals: Press 24 h Totals.
9. Press EXIT.
10. Press START.

PCA/Monitoring Trend Data
Note: This function requires use of monitoring module(s)
1. Press CHANNEL SELECT on the Monitoring Module.
2. Press OPTIONS.
3. Press PCA/Monitoring Trend data.
4. To exit: Press MAIN.
5. Press Main Screen.

Give a Bolus Dose
1. Press CHANNEL SELECT.
2. Press Bolus Dose.
3. Set key to Program position or enter authorization code (if enabled).
4. Enter bolus dose amount.
5. Lock door.
6. Press CONFIRM.
7. Review settings and press START.

Stopping Bolus, Loading or PCA Dose
1. Press CHANNEL SELECT key.
2. Press Stop Bolus/Loading or PCA.
3. Press YES or NO.

Note: Programmed settings will resume.

Change Dose Request Cord Setting
1. Press CHANNEL SELECT key.
2. Press OPTIONS.
3. Press Dose Request Set-up.
4. Choose desired Dose Cord Profile. (1=light flashes, 2=light on, 3=light off)
5. Press CONFIRM.
6. Press START.

Attach Dose Request Cord
1. Align red mark on latching connector with red mark on Dose Request Cord attachment.
2. Insert latching connector on the cord into Dose Request Cord attachment on PCA Module.

Detach Dose Request Cord
1. Hold body of latching connector on the cord and pull straight away from Dose Request Cord attachment on the PCA Module.
<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check Syringe</td>
<td>- Plunger grippers opened during infusion and then closed. Infusion stops on affected channel.</td>
<td>Securely lock plunger grippers, press CHANNEL SELECT key, and reselect syringe.</td>
</tr>
<tr>
<td></td>
<td>- Syringe barrel clamp opened during infusion and then closed.</td>
<td>Securely lock syringe barrel clamp and press RESTART key.</td>
</tr>
<tr>
<td></td>
<td>- Syringe plunger not captured while in idle mode. System alarms immediately to indicate potential siphoning condition. If security door is closed and syringe plunger is not captured, the system will immediately alarm.</td>
<td>Check for potential siphoning. Ensure administration set clamp (roller/slide) is in closed position. Securely lock plunger grippers over syringe plunger.</td>
</tr>
<tr>
<td>PCA Pause Alarm</td>
<td>PCA infusion has paused due to a decline in respiratory status.</td>
<td>Assess patient status per hospital policy. Press CONFIRM once patient status and monitoring values have been addressed. Press RESTART key per hospital policy. To view trigger of PCA Pause Alarm, Press CHANNEL SELECT, Press OPTIONS, Press DRUG EVENT HISTORY, Press Up/Down key to view text for monitoring value causing PCA Module to pause. Press EXIT and then START.</td>
</tr>
<tr>
<td>Drive Not Engaged</td>
<td>Drive system disengaged during operation.</td>
<td>Open and close plunger grippers. Ensure syringe is properly installed.</td>
</tr>
</tbody>
</table>
### Alarms and Troubleshooting: Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel Error</td>
<td>Error detected on infusing channel. Infusion stops on affected channel.</td>
<td>To silence alarm and continue operation of unaffected channels, press <strong>CONFIRM</strong> soft key. Replace channel with an operational instrument, as required. Service by qualified personnel is required.</td>
</tr>
<tr>
<td>Syringe Driver Head Error</td>
<td>Noninfusing channel, with plunger grippers open, senses excessive pressure being applied downward on Drive Head. <strong>OCCLUSION</strong> scrolls in Channel Message Display.</td>
<td>To silence alarm and continue normal operation, press <strong>CONFIRM</strong> soft key.</td>
</tr>
</tbody>
</table>

### Messages

<table>
<thead>
<tr>
<th>Messages</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
</table>
| Max Limit Reached   | Programmed Max Limit has been reached over time period specified. Infusion paused until time limit has expired. | To silence alarm, press **SILENCE** key  
**NOTE:** The device will re-alarm if the dose request cord is pressed again while in a Max Limit state.  
To change Max Limit, press **CHANNEL SELECT**; press **SETUP** soft key and unlock door or enter Authorization Code applicable for current Security Access Level. |
| PCA Not In Secure Location | PCA Module is not in preferred location to allow locking to the PC Unit. Device is not in a tamper evident position. | Detach PCA Module from current position and reattach to immediate right of the PC Unit.                                                                  |
| Syringe Not Recognized | Installed syringe of unknown type and size.                              | Select and confirm correct syringe type and size, and then press **CONFIRM**; or use a syringe type and size that system can automatically and correctly identify. Ensure compatible syringe is loaded. For a list of compatible syringes, refer to Compatible Sets section of this Directions for Use. |
QUICK REFERENCE GUIDE

Operator Precautions:
To ensure proper operation of the Alaris® System (formerly known as "Medley® System"), user must be familiar with related features, disposables, administration sets, set-up and programming.

This guide is not intended to be comprehensive instructions for the setup and operation of the Alaris System. For complete instructions along with Warnings and Cautions, refer to Alaris System Directions for Use (v8).

PROGRAMMING

Setting Alarm Limits
1. Press CHANNEL SELECT.
2. Press LIMITS.
3. Select limit to be changed.
4. Enter a numeric value using keypad or up/down arrow keys.
5. Press CONFIRM.

Trend Data
1. Select TREND.
2. Press PAGE UP and PAGE DOWN to navigate through trend data pages. To move cursor bar press up or down arrow keys.
3. Press ZOOM to change time period.
4. To exit press EtCO₂ Main.

PCA/ETCO₂ Trend Data
(Available only with an Alaris® PCA Module)
1. Press OPTIONS.
2. Select PCA/ETCO₂ Trend Data. Navigate as described above in section titled Trend Data.

Change Waveform Height
1. Press OPTIONS.
2. Select WAVEFORM HEIGHT.
3. Select 60mmHg or 99mmHg.

Change Waveform Time Scale
1. Press OPTIONS.
2. Select WAVEFORM TIME SCALE.
3. Select 5 or 10 seconds (for lower respiratory rates select 10 seconds).

Pre-Silencing Alarm
1. Press SILENCE to pre-silence monitoring alarms for two minutes.

Note: Infusion alarms will not be silenced.

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### Alarms

<table>
<thead>
<tr>
<th>High Priority Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Breath Detected</td>
<td>No breath has been detected for a specified period of time.</td>
<td>Assess patient condition. Check Microstream® Disposable. Confirm correct disposable is chosen. Confirm correct disposable placement.</td>
</tr>
<tr>
<td>High EtCO₂</td>
<td>EtCO₂ value is above the specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>Low EtCO₂</td>
<td>EtCO₂ value is below the specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>High RR</td>
<td>Respiratory Rate is above the specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>Low RR</td>
<td>Respiratory Rate is below the specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>High FiCO₂</td>
<td>FiCO₂ value is above the specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>Disconnect</td>
<td>Purging operation failed.</td>
<td>Check Microstream® Disposable. Obtain a new Microstream® Disposable. Attach Microstream® Disposable to patient and module.</td>
</tr>
<tr>
<td>Occluded Disposable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Messages

<table>
<thead>
<tr>
<th>Message (in progress)</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autozero</td>
<td>EtCO₂ Module performs a baseline by sampling CO₂ present in ambient air.</td>
<td>Wait for the module to complete its auto-zeroing function. After the auto-zero cycle is complete, the module will begin measurement again. No user intervention is required.</td>
</tr>
<tr>
<td>Clearing Disposable</td>
<td>Microstream® Disposable has become blocked.</td>
<td>Check Microstream® Disposable. Wait for purging to complete.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EtCO₂ Waveform Examples

Normal Waveform Example = Normal Ventilation; 35-45 mmHg
A- B: Baseline period of no CO₂, end of inhalation
B- C: Rapid rise in CO₂
C- D: Alveolar plateau
D- E: Inhalation

Abnormal Waveform Examples - Not necessarily associated with alarms

Hypoventilation
Possible Causes:
• Overmedication

Hyperventilation
Possible Causes:
• Respiratory distress
EtCO₂ Waveform Examples (Continued)
Abnormal Waveform Examples - Not necessarily associated with alarms

Partial Airway Obstruction
Possible Causes:
• Relaxation of upper airway
• Head position

Hypoventilation with Shallow Breathing
Possible Causes:
• Medication effect
• Low tidal volume

No Breath Detected
Possible Causes:
• Apnea
• Very shallow breathing
• Overmedication
• Displaced cannula
FAMILY MEMBERS & VISITORS

- The patient is on Patient Controlled Analgesia (PCA) therapy for pain management.

- For patient safety, **ONLY THE PATIENT** can press the PCA button to administer pain medication.

- Thank you for helping us to keep your loved one safe!

- Questions? Please ask a nurse.