

TITLE

INFUSION PUMPS FOR MEDICATION & PARENTERAL FLUID ADMINISTRATIONSCOPE

Provincial, Clinical

DOCUMENT

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APPROVAL LEVEL

Executive Leadership Team

SPONSOR

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Patient Safety

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Not applicable

PARENT DOCUMENT TYPE & TITLE

Infusion Pumps for Medication & Parenteral Fluid Administration
Policy Level 1

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

If you have any questions or comments regarding the information in this procedure, please contact the Policy & Forms Department at policy@albertahealthservices.ca. The Policy & Forms website is the official source of current approved policies, procedures, directives, and practice support documents.

OBJECTIVES

- To describe the process for the management of an infusion pump involved in an **adverse event** or **close call**.
- To outline the process for the management of soft stops/limits and hard stops/limits for infusion pumps with **dose error reduction software (DERS)**.

APPLICABILITY

Compliance with this procedure is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary). This procedure does not limit any legal rights to which you may otherwise be entitled.

PROCEDURE ELEMENTS**1. Education and Support**

- 1.1 Refer to the *Standards and Guidelines for Infusion Pump Education* document and the Provincial Infusion Pump Education Insite page for additional information regarding infusion pump education.
 - a) The Alberta Health Services Health Professions Strategy & Practice *Standards and Guidelines for Infusion Pump Education* provides standards for the frequency of infusion pump education, skill and

performance/competency development, requirements for documentation, and guidelines for key stakeholders who are responsible for providing and facilitating education about infusion pumps.

- 1.2 Refer to the Alberta Health Services *Provincial Parenteral Manual* monographs, (or Zone legacy parenteral manuals when a provincial monograph does not exist), for guidance on medication/parenteral fluids that require administration via an infusion pump.

2. Infusion Pump Maintenance and Repair

- 2.1 When the user guide or manual states that only a specialized technician or biomedical engineer may troubleshoot or repair the pump, no other **health care providers** shall perform the task in order to maintain warranty protection and to ensure the asset meets all recommended manufacturer specifications.
- 2.2 All service and support pertaining to any infusion pump shall be recorded and archived in a controlled Maintenance Management System by Clinical Engineering. These records shall be associated by manufacturers' serial number or by an inventory control number assigned by Alberta Health Services.

3. Adverse Events and Close Calls

- 3.1 In the case of an adverse event that results in patient harm due to a problem with an infusion pump, follow the:
 - a) Alberta Health Services *Immediate and Ongoing Management of Clinically Serious Adverse Events* Guideline;
 - b) Alberta Health Services Product Quality & Safety "PLEASE" Quarantine Process. Information on the "PLEASE" Quarantine Process can be found on the Alberta Health Services Product Quality and Safety Insite page.
- 3.2 Report adverse events and close calls as described in the Alberta Health Services *Reporting of Clinical Adverse Events, Close Calls and Hazards* Policy.

4. Independent Double-checks

- 4.1 Refer to the Alberta Health Services *Management of High-alert Medications* Policy, Procedure and guidelines for a list of **high-alert medications** requiring an **independent double-check**.
 - a) Be aware of Zone, program or site-based additional medications that require an independent double-check.
- 4.2 Independent double-check of pump settings shall be performed for all infusion pumps, including infusion pumps with dose error reduction software (DERS) for those medication(s) identified as requiring an independent-double check as per the Alberta Health Services *High-Alert Medications* Procedure.

- a) Refer to the Alberta Health Services *Independent Double-check* Guideline for direction on how to perform an independent double-check of pump settings.
- 4.3 The manual programming of non-standardized medication concentrations shall be verified through an independent double-check. Refer to Alberta Health Services *Standardized Medication Concentrations for Parenteral Administration* Policy for further information.
- 5. Dose Error Reduction Software (DERS)**
- 5.1 Soft Stops/Limits –
- a) For infusion pumps with dose error reduction software, the **drug library** shall contain soft stop/limits for all medications.
 - b) See Appendix A: *Management of Soft Stops/Limits in Infusion Pumps with Dose Error Reduction Software* for information on actions to take when a soft stop/limit is encountered.
- 5.2 Hard Stops/Limits –
- a) For infusion pumps with dose error reduction software, the drug library shall contain hard stop/limits, for, at a minimum, all high-alert medications listed in the Alberta Health Services *Management of High-alert Medications* Policy, Procedure and guidelines.
- 5.3 See Appendix B: *Management of Hard Stops/Limits in Infusion Pumps with Dose Error Reduction Software* for information on actions to take when a hard stop/limit is encountered.

DEFINITIONS

Adverse event means an event that could or does result in unintended injury or complications arising from health care management, with outcomes that may range from death or disability to dissatisfaction, or require a change in care, such as prolongation of hospital stay.

Authorized prescriber means a health care professional who is permitted by Federal and Provincial legislation, her/his regulatory college, Alberta Health Services and practice setting (where applicable) to prescribe medications.

Close call means an event in which a patient is exposed to or involved in a situation with the potential for harm. For one or more reasons the danger did not reach the patient (that is, no harm occurred).

Dose error reduction software (DERS) means pre-determined programming for compatible pumps with digital memory, including minimum and maximum doses and minimum and maximum rates of administration, for given standard concentrations of solution. Pumps that use this software are also known generally as “SMART” or “smart technology” pumps.

Drug library means a digital memory, often for use with an electronically loadable infusion pump, containing a plurality of medication information entries, including, but not limited to, minimum, default and maximum parameters for concentration, delivery rate, dose and bolus size. (Adapted from Baxter/United States Patent and Trademark Office [2013])

Hard stops/limits means a pre-set alert, in an infusion pump, that will notify the user that the dose, route or concentration selected is out of the institution-determined safe range for that medication, and will not allow the infusion to be administered unless the pump is reprogrammed within the acceptable range. (Provincial Infusion Pump Education Working Group, 2010)

Health care professional means an individual who is a member of a regulated health discipline, as defined by the *Health Disciplines Act* [Alberta] or the *Health Professions Act* [Alberta], and who practises within scope and role.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

High-alert medications means medications that bear a heightened risk of causing significant patient harm when used in error. (Institute for Safe Medication Practices [ISMP], 2012)

Independent double-check means a verification process whereby a second health care provider conducts a verification of another health care provider's completed task. The most critical aspect is to maximize the independence of the double-check by ensuring that the first health care provider does not communicate what he or she expects the second health care provider to see, which would create bias and reduce the visibility of an error. (Institute for Safe Medication Practices [ISMP], 2005)

Infusion pumps means all pumps used to control delivery of parenteral fluid and/or medicated solutions, including but not limited to syringe, epidural, patient-controlled analgesia (PCA), dose error reduction software (DERS; also known as "SMART" or "smart technology"), "general purpose", large volume and ambulatory pumps.

Soft stops/limits means a pre-set alert, in an infusion pump, that will notify the user that the dose, rate or concentration selected is out of the anticipated range for that medication. However, soft stops/limits can be overridden by the user, and the medication can still be infused without changing the dose error reduction software pump settings. (Provincial Infusion Pump Education Working Group, 2010)

REFERENCES

- Appendix A: *Management of Soft Stops/Limits in Infusion Pumps with Dose Error Reduction Software*
- Appendix B: *Management of Hard Stops/Limits in Infusion Pumps with Dose Error Reduction Software*
- Alberta Health Services Governance Documents:
 - *Infusion Pumps for Medication and Parenteral Fluid Administration Policy (#PS-70)*
 - *Reporting of Clinical Adverse Events, Close Calls and Hazards Policy (#PS-11)*
 - *Immediate and Ongoing Management of Clinically Serious Adverse Events Guideline (#PS-11-01)*
 - *Invasive Infusion Line and Tubing Verification Policy (#PS-15)*
 - *Government of Alberta Health & Alberta Health Services Emergency Medical Services Provincial Medical Control Protocols: Adult and Pediatric*
- Alberta Health Services Resources:
 - *Alberta Health Services Health Professions Strategy & Practice Standards and Guidelines for Infusion Pump Education*
- Non-Alberta Health Services Documents:
 - Accreditation Canada QMentum Program, *Medication Management Standards* (For Surveys Starting After: January 1, 2014)

VERSION HISTORY

Date	Action Taken
July 28, 2015	Initial approval date
January 04, 2016	Initial effective date

APPENDIX A

Management of Soft Stops/Limits in Infusion Pumps with Dose Error Reduction Software

Soft stops/limits may be overridden after the **health care professional** ensures it is appropriate and safe to do so. Follow the process below when a soft stop/limit is encountered:

1. Confirm the correct medication order has been programmed by ensuring:
 - a) the correct care area/drug library profile has been selected;
 - b) the correct medication/parenteral fluid has been selected;
 - c) the correct dose has been entered into the infusion pump;
 - d) the correct concentration has been entered into the infusion pump; and
 - e) the correct rate has been entered into the infusion pump.
2. If the infusion pump was incorrectly programmed, re-program the infusion pump with the correct values.
3. If the health care professional administering the medication deems the ordered dose, concentration or rate to be clinically appropriate, the soft stop/limit may be overridden and the medication may be infused.
4. If the health care professional determines that it is safe to override the soft stop/limit, the health care professional should:
 - a) in the case of a dose soft stop/limit, contact the authorized prescriber for direction on how to safely proceed (as this could indicate a potential prescribing error); or
 - b) in the case of a rate or concentration soft stop/limit, refer to the parenteral monograph and/or consult with a pharmacist or a nursing supervisor for direction on how to safely proceed (as this could indicate a potential administration error).
 - c) Record in the patient's health record:
 - i. any changes made to the infusion pump settings; and
 - ii. the rationale for overriding a soft stop/limit.
5. If the soft stop/limit is encountered frequently, and the limit is thought to be clinically inappropriate (e.g., soft stop/limit is inconsistent with current clinical evidence or practice), a request can be submitted, via the Alberta Health Services Infusion Pump website portal (Our Teams/Departments> Provincial Medication Safety>Infusion Pumps) for review of the soft stop/limit.

Warning: If a health care professional programs the infusion pump and disregards or disables the dose error reduction software limits, the safety features of that infusion pump will not be available and patient safety will be at risk.

Note: Refer to section 6 regarding dose error reduction software, in the Alberta Health Services *Infusion Pumps for Medication & Parenteral Fluid Administration Policy*.

APPENDIX B

Management of Hard Stops/Limits in Infusion Pumps with Dose Error Reduction Software

Hard stops/limits will only allow the medication/parenteral fluid to be administered within the programmed acceptable ranges.

When a health care professional encounters a hard stop/limit, the health care professional will not be able to proceed with administration of the medication/parenteral fluid. Follow the process below when a hard stop/limit is encountered:

1. Confirm the correct medication order has been programmed by ensuring:
 - a) the correct care area/drug library profile has been selected;
 - b) the correct medication/parenteral fluid has been selected;
 - c) the correct dose has been entered into the infusion pump;
 - d) the correct concentration has been entered into the infusion pump;
 - e) the correct rate has been entered into the infusion pump.
2. If the infusion pump was incorrectly programmed, re-program the infusion pump with the correct values.
3. If the verified dose, rate or concentration continues to exceed the hard stop/limits, the health care professional shall contact the authorized prescriber to obtain a new medication order that is within the hard stop/limit.
4. If, after contacting the authorized prescriber, it is determined that the medication order is appropriate and the medication should be infused beyond the hard stop/limit, the health care professional shall:
 - a) Obtain an order from the authorized prescriber to infuse the medication bypassing the dose error reduction software (i.e., utilize basic infusion mode).
 - b) Ensure an independent double-check is completed per the Alberta Health Services *Independent Double-check* Guideline.
 - c) Infuse the medication, bypassing the dose error reduction software.
 - d) Record in the patient's health record:
 - i. any changes made to the infusion pump settings;
 - ii. the rationale for infusing the medication beyond the hard stop/limit.
5. If the hard stop/limit is encountered frequently, and is thought to be clinically inappropriate (e.g., hard stop/limit is inconsistent with current clinical evidence or practice), a request can be submitted, via the Alberta Health Services SMART Infusion Pump website portal (Our Teams/Departments>Provincial Medication Safety>Infusion Pumps), for review of the hard stop/limit.

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APPENDIX B continued

Warning: If a health care professional programs the infusion pump and disregards or disables the dose error reduction software limits, the safety features of that infusion pump will not be available and patient safety will be at risk.

Note: Refer to section 6 regarding dose error reduction software, in the Alberta Health Services *Infusion Pumps for Medication & Parenteral Fluid Administration* Policy.