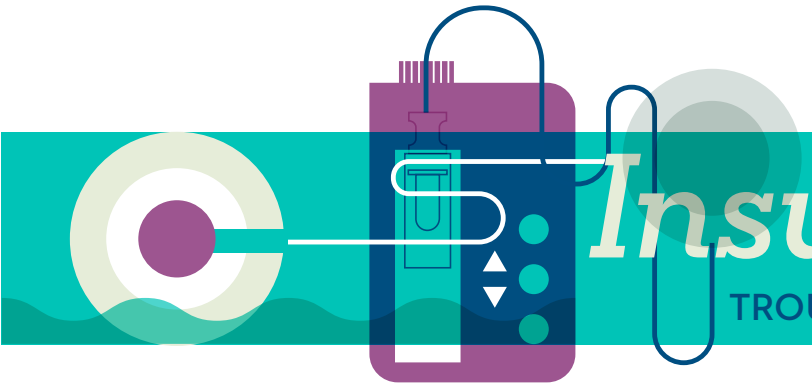

Insulin INFUSION SETS

TROUBLESHOOTING GUIDE

Insulin pump therapy functions with multiple components including the pump, reservoir, insulin, infusion set and the user. All must work seamlessly to ensure healthy blood glucose levels.

Diabetes care and education specialists must be prepared to troubleshoot all aspects of insulin pump therapy and assist individuals when unexplained hyperglycemia occurs. In one randomized controlled trial involving several hundred insulin pump users, more than two-thirds experienced unexplained hyperglycemia at least once per month. Sources of unexplained hyperglycemia may of a mechanical, behavioral or physiologic/metabolic nature.

Given the multitude of factors that influence glycaemia, it is imperative that clinicians and people with diabetes develop effective problem-solving skills for detection, prevention and treatment of problems arising from continuous subcutaneous insulin infusion. Following a step-by-step troubleshooting process can help prevent rapid deterioration of glucose management and avoid unnecessary/ineffective corrective measures.

TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Verify that the pump is delivering insulin into the body.

Possible Causes	Corrective/Preventative Action
Interruption of insulin delivery	If the individual is vomiting or showing other symptoms of DKA (extreme hyperglycemia, muscle aches, fruity breath, deep/labored breathing, delirium), advise them to call 911 and go to the emergency room immediately. If not showing acute signs of DKA, advise the person with diabetes to check for ketones in blood; check urine if a blood ketone monit or is not available. If ketones are present in significant amounts (≥ 0.6 mmol/L or greater than “trace”):

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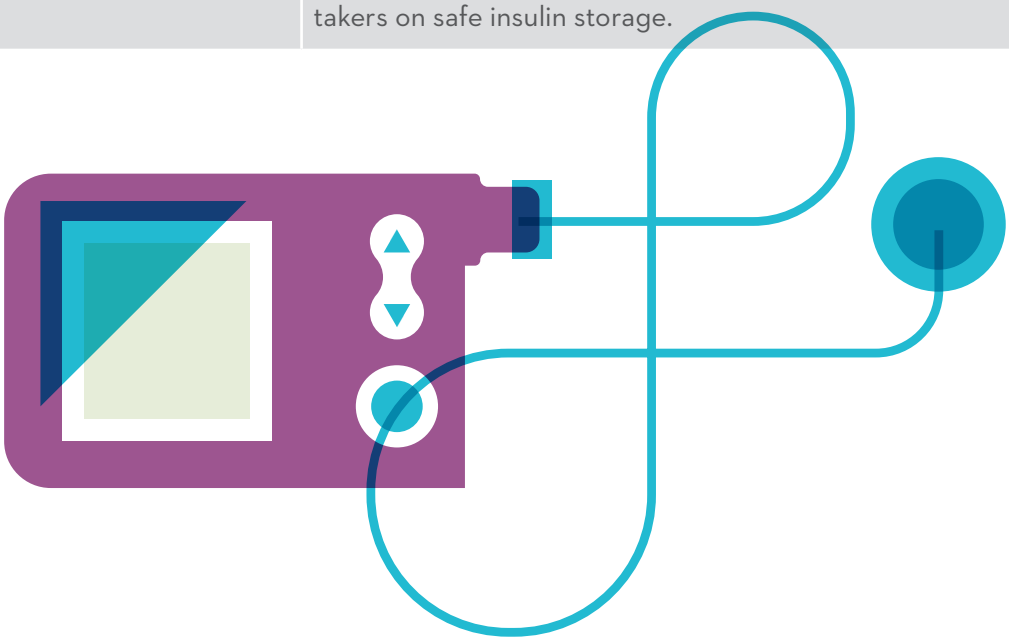
INSULIN INFUSION SETS

Trouble-shooting Guide

TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Verify that the pump is delivering insulin into the body.

Possible Causes	Corrective/Preventative Action
Interruption of insulin delivery (*continued from previous page)*	1. Instruct individuals to inject supplementary bolus via syringe or pen and enter the data into the pump (disconnect pump from infusion site, deliver equivalent bolus) so that insulin-on-board will be calculated properly. 2. Advise the individual to replace the infusion set and tubing, and use a fresh insulin vial to fill a new cartridge/reservoir. 3. Advise the individual to drink water to prevent dehydration and facilitate elimination of ketones via urination. If ketones are NEGATIVE, they may bolus with the pump. Instruct to follow steps 1-3 above if glucose level does not decline within two hours.
Insulin spoilage	Inquire about storage of the insulin vial currently being used. Exposure to elevated temperatures can result in partial or complete degradation. Exposure of the pump/tubing to high temperatures or direct sunlight can cause similar problems. Were there circumstances (eg, travel, beach, spa, items left in hot car) that could have exposed insulin to extreme temperatures? If in doubt, suggest replacement of the insulin vial and/or changing the pump's insulin cartridge and tubing. Educate the individual and care takers on safe insulin storage.



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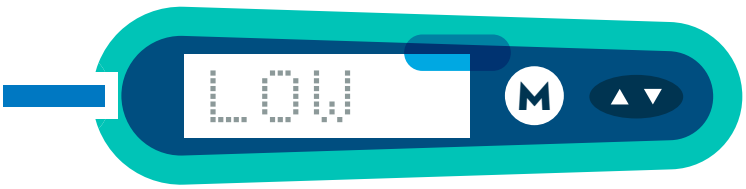
INSULIN INFUSION SETS

Trouble-shooting Guide

TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Verify that the pump is delivering insulin into the body.	
Possible Causes	**Corrective/Preventative Action**
Incorrect insulin being used	Verify that the pump's cartridge was filled with rapid-acting insulin, and not intermediate or long-acting/basal insulin.
Pump settings are incorrect	Check the pump's clock as well as basal and bolus calculation settings to ensure accuracy.
Infusion set displacement	Even if taped to the skin, it is possible for the infusion set to displace. Examine the site for loose tape and moisture, and see if an insulin "smell" is present. Change infusion set if displacement is detected or suspected.

Consideration: Consider physiologic implications.	
Possible Causes	**Corrective/Preventative Action**
Menstrual cycle	For several days prior to menses, many women experience elevated glucose levels. Consider using a secondary basal pattern until menstruation occurs.
Illness/infection/injury	Assess overall health status; refer to primary physician if symptoms of illness are present. Consider use of temporary basal increase until symptoms diminish.
New medication	Inquire about recent use of steroid medications / injections, elimination (or missed dose) of non-insulin diabetes medication, or the addition (or dose increase) of other medications that can raise glucose levels.
Recent hypoglycemia	Elevated glucose could be the result of counterregulatory hormone production ("rebound") or overtreatment of the low. Educate on proper treatment of hypoglycemia.



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INSULIN INFUSION SETS

Trouble-shooting Guide

TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Assess lifestyle changes.	
Possible Causes	**Corrective/Preventative Action**
Changes in eating patterns (higher fat foods, more frequent eating, larger portions)	Adjust/educate as indicated.
Increased stress	Discuss stress management techniques. Refer for mental health counseling. Consider insulin adjustment (temporary basal increase) when stress is anticipated.
Decrease in physical activity	A reduction in insulin sensitivity may be causing a marked glucose elevation. Discuss resuming normal activities or making adjustments to insulin doses until normal activity can resume.
Anaerobic/competitive activities	Production of counterregulatory hormones during some forms of exercise can cause an acute rise in blood glucose. Supplementary insulin may be needed to prevent the rise.
Changes in sleep cycle	Sleep deprivation may increase counterregulatory hormone production. Excessive sleep can impair insulin sensitivity. Refer to a sleep specialist; consider use of a secondary basal program until the problem is resolved.

Consideration: Screen for other sources of hyperglycemia.	
Possible Causes	**Corrective/Preventative Action**
Under-bolus (or missed bolus) for food	Evaluate carbohydrate content of recent meals/snacks. Evaluate/adjust bolus dose calculation formulas. Check pump history to confirm delivery of proper doses. (Re)Educate on carb counting technique, importance of bolusing for all meals/snacks, and proper bolus timing in relation to meals.

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TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Screen for other sources of hyperglycemia.	
Possible Causes	**Corrective/Preventative Action**
Under-bolus (or missed bolus) for food *(continued)*	Unexpected/delayed glucose rises can occur in individuals with gastroparesis and following consumption of high-fat meals. Large amounts of dietary protein (or protein consumed in the absence of carbohydrate) can also contribute to an unexpected glucose rise.
Glucose meter inaccuracy	Verify that fingers were clean, proper testing procedures were followed, test strips were stored properly and are within the expiration date. Use control solution to confirm meter accuracy. Replace meter and strips if outside of reference range.

Consideration: Recurrent infusion set/site issues require prompt attention and correction. Some, but not all, are preventable through proper training/education.	
Possible Causes	**Corrective/Preventative Action**
Bleeding	Mild, temporary bleeding at infusion sites may occur periodically. It is not typically dangerous, but it may result in malabsorption of insulin or clogging of the cannula. At the first sign of blood at the infusion site or in the tubing, the individual should be instructed to change the infusion set and move to a new site. If certain body parts or sites are more prone to bleeding, people with diabetes should be advised to avoid these areas.
Highs after site changes	If elevations in glucose occurs on a routine basis following infusion set changes, these strategies may help: 1. Change the infusion set prior to a meal and administer a full meal bolus soon after changing the set. 2. Ensure both tubing and catheter have been fully primed with each infusion set change. 3. Consider an extra small bolus once the new infusion set is in place. 4. Keep the old set on the skin for an hour or two to prevent leakage of recently-administered insulin.

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TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Recurrent infusion set/site issues require prompt attention and correction. Some, but not all, are preventable through proper training/education.

Possible Causes	Corrective/Preventative Action
Discomfort	For those who experience significant discomfort when inserting their infusion set, a number of options are available: ■ Inserting the infusion set needle (or introducer needle) in one quick step ■ Using a spring-loaded insertion device (ensuring the fastest, most precise insertion possible) ■ Switching to a shorter/higher-gauge introducer needle ■ Temporarily numbing the skin prior to insertion with ice or topical anesthetics containing lidocaine In some instances, a temporary "twinge" of pain can occur even with an infusion set that is properly inserted and working as designed. If the pain does not subside in an hour, the infusion set should be changed and moved to a new site. For those who often experience prolonged pain after the infusion set has been inserted, relief can come from use of a short, flexible catheter (rather than a steel needle or longer cannula) and avoiding sites that are susceptible to frequent movement or trauma.

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TROUBLESHOOTING UNEXPLAINED HYPERGLYCEMIA

Consideration: Recurrent infusion set/site issues require prompt attention and correction. Some, but not all, are preventable through proper training/education.

Possible Causes	Corrective/Preventative Action
Frequent occlusions	If occlusion alarms occur more than once per month, it is possible that the pump's pressure sensor is malfunctioning. Contact the pump manufacturer to troubleshoot. If the pump is functioning properly, consider the following: ■ Switch to a steel-needle infusion device or a flexible catheter that has multiple ports for ensuring uninterrupted insulin flow. ■ Avoid using sites that are subject to pressure from restrictive clothing. ■ Change to a site with more subcutaneous fat. ■ Use a shorter catheter. ■ Change the infusion set more frequently.
Bent Cannula	Flexible catheters may bend below the skin if the infusion set is hit/pressed, or if the cannula makes contact with flexing muscles. A bent cannula may or may not impede insulin flow, but it will almost always result in skin irritation which, in turn can impair insulin absorption. If bent cannulae are observed often when the infusion set is removed, individuals may be advised to: ■ Choose a body part or site that has ample subcutaneous fat and is away from working muscles. ■ (If using a 90-degree set): Switch to a shorter cannula or angled infusion set. ■ (If using an angled set): Switch to a shorter cannula or insert at a sharper (shallower) angle. ■ (If using any type of flexible catheter): Switch to a steel needle infusion set.

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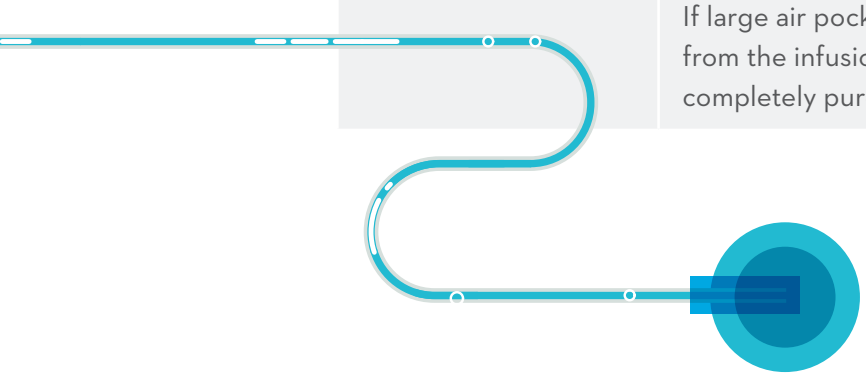
INSULIN INFUSION SETS

Trouble-shooting Guide

TROUBLESHOOTING ACUTE INFUSION SET/SITE ISSUES

Consideration: Virtually all insulin pump users will experience acute issues with infusion sets/sites on occasion.

Possible Causes	Corrective/Preventative Action
Infusion set displacement	Examine the infusion site to verify that the infusion set is secure against the skin. If it is partially or completely peeled away from the skin, remove and replace the set immediately. With infusion sets that have a window allowing visualization of the cannula entering the skin, check to make sure that the full cannula has been inserted. If more than a few millimeters of cannula are exposed, remove the infusion set and instruct the person with diabetes to insert the introducer needle completely when inserting a new set.
Occlusion in tubing or catheter	Prior to or during training, test the individual's ability to hear/detect alarms. An inability to detect alarms may require selection of a different pump, switching to/from audible/vibratory alerts, or training a partner on alarm recognition/response. With any pump alarm indicating that a blockage has taken place, the user should change their tubing and infusion set immediately.
Silent occlusions (No occlusion alarm; elevated glucose that doesn't come down with correction bolus, but no ketones present)	Consider different catheter type – steel needle or dual-port cannula.
Prolonged disconnection	Check the infusion site to confirm that the tubing is connected securely to the infusion set. If it is not, reconnect immediately and administer a bolus to replace basal insulin that was missed. Instruct the user to limit disconnection times to no more than 90 minutes.
Air in the system	Verify that the tubing was primed and that an appropriate dose was administered to complete priming of the cannula (when appropriate). If large air pockets are detected in the tubing, disconnect the tubing from the infusion set and re-prime the tubing until air has been completely purged.



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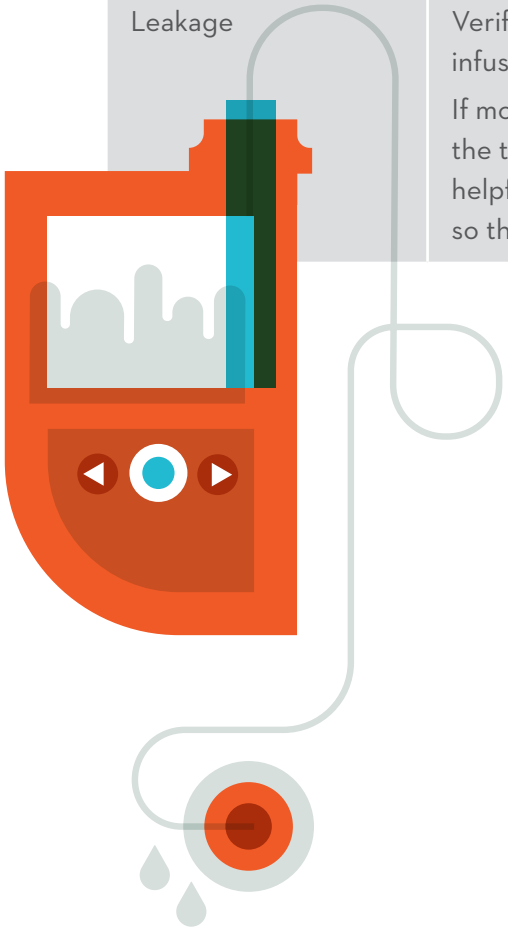
INSULIN INFUSION SETS

Trouble-shooting Guide

TROUBLESHOOTING ACUTE INFUSION SET/SITE ISSUES

Consideration: Virtually all insulin pump users will experience acute issues with infusion sets/sites on occasion.

Possible Causes	Corrective/Preventative Action
Malabsorption	In general, the infusion set should be changed and moved to a new location if any of the following are present: ■ Blood at the site or in the tubing ■ Pain/discomfort ■ Redness, warmth or inflammation ■ If the same infusion set has been worn for more than three days Wearing an infusion set for too long in the same spot will usually hinder insulin absorption. The frequency of site changes can be determined by reviewing the pump's prime history or downloading the pump. Although the acceptable length of wear is person-specific, some individuals may over-extend use of infusion sets due to cost concerns or anxiety surrounding set changes. Discuss this so that reasonable solutions can be developed.
Leakage	Verify that the connections between the insulin cartridge, tubing and infusion set are secure. If moisture is present at the infusion site or the user can "smell" insulin, the tubing and infusion set should be changed immediately. It can be helpful to expose individuals to open insulin during their initial training so that they can recognize its odor.



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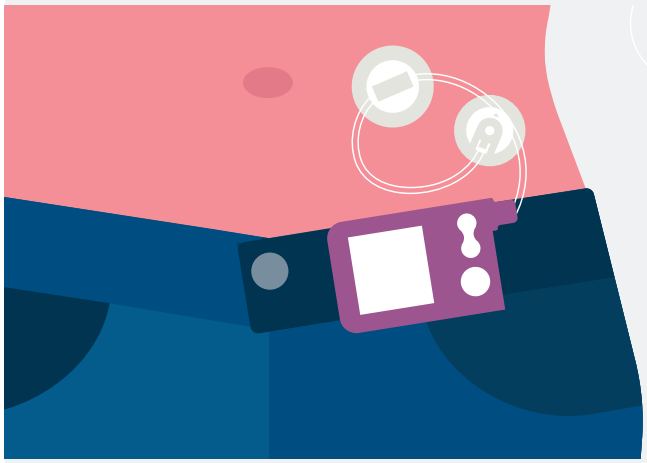
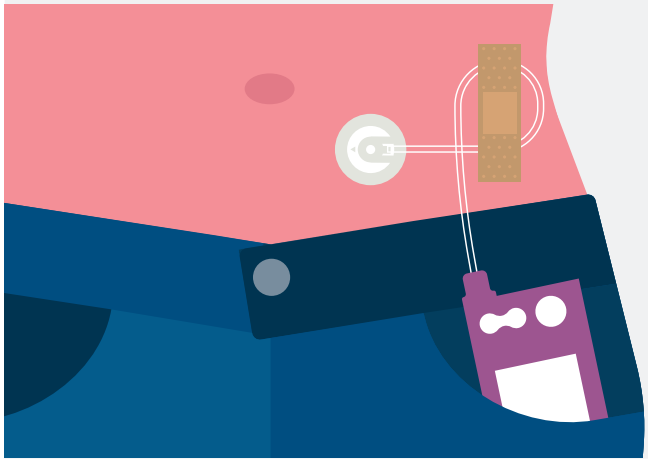
TROUBLESHOOTING CHRONIC INFUSION SET/SITE ISSUES

Consideration: Recurrent infusion set/site issues require prompt attention and correction. Some, but not all, are preventable through proper training/education for the person with diabetes.

Possible Causes	Corrective/Preventative Action
Adhesion	When adhesion failures occur repeatedly, many individuals benefit from simply moving their infusion sets to a body part that moves/stretches/pulls/perspires less, such as the upper buttocks. Other strategies for improving adhesion: ■ Prior to insertion, make sure the skin is clean and dry, free of oils, lotions and perfumes. ■ Hairy sites should be shaved with (not against) the direction of hair growth the day prior to inserting the infusion set. ■ Adhesive agents may be applied to the skin prior to insertion. ■ Over-bandages may be used to improve adhesion. With over-bandages, a hole may be cut in the center to allow access to the connect/disconnect mechanism. ■ To minimize the risk of accidental pull-outs due to snagged/pulled tubing, consider use of an infusion set that has a secondary disconnect site that adheres to skin. Otherwise, a "safety loop" can be made proximal to the disconnect mechanism. A small piece of adhesive tape placed over the loop can help to reduce risk of pulling directly on the infusion set.



Infusion set with secondary disconnect mechanism



Tubing with safety loop

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TROUBLESHOOTING CHRONIC INFUSION SET/SITE ISSUES

Consideration: Recurrent infusion set/site issues require prompt attention and correction. Some, but not all, are preventable through proper training/education.

Possible Causes	Corrective/Preventative Action
Infection	Infections at infusion sites are relatively rare. However, all individuals should be careful not to allow the infusion set needle (or introducer needle) to touch anything prior to insertion, and to wear each infusion set for only two to three days. Users with a history of cellulitis, compromised immunity, staph or other skin infections are at an increased risk of site infections. A strong antiseptic should be applied to the skin prior to infusion set insertion. Individuals should be provided with signs/symptoms of site infections and instructed to seek medical attention at the first sign of erythema, edema, warmth, pus and blistering.
Skin allergies	A variety of skin barriers can be used to minimize exposure to infusion set materials that may cause allergic reactions. In some instances, use of OTC antihistamine medications such as diphenhydramine can prevent symptoms and provide relief. For extreme/stubborn allergic reactions, individuals should be referred for dermatologic care.
Lipodystrophy	Insulin absorption is impaired when infused into areas of skin that are affected by lipoatrophy or lipohypertrophy. Palpation of infusion sites at each office visit can aid in the detection of lipodystrophy. Feel for unusual indentations, inflammation, softness and hardness below the skin surface. Affected areas must be avoided to ensure proper and consistent insulin absorption. Note that temporary, minor inflammation is common at recently-used infusion sites and may not indicate the presence of lipodystrpohy. All insulin pump users should be instructed on proper infusion site rotation in order to prevent the development of lipodystrophies. This includes selection of appropriate body parts and equal use of a multitude of specific sites within each body part.

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