

ALERT: Alarm Not Activated after Infusion Pump Tubing Incorrectly Loaded

ISMP Canada has recently received two reports involving over-infusion of heparin and morphine intravenously with the Baxter Flo Gard pump, model 6201. In each case the infusion rate was correctly set and the display of the volume delivered corresponded to the infusion rate, but the actual amount delivered was much greater. In both circumstances the pump generated no alarm and the nurses noted the over-infusions after considerable volumes were missing from the infusion bags. The nurses involved in these incidents were experienced users of the pump and considered to be “senior” members of staff.

The first case involved over-infusion of intravenous heparin. An infusion of 25,000 units in 250 mL was initiated at 1,400 units/hour, with the pump set to deliver 14 mL/hour. Approximately one hour after the infusion was begun, the nurse noticed that almost the entire 250 mL had been infused. Fortunately, the patient suffered no serious harm.

In the second case, an intravenous morphine drip was initiated on a critically ill patient. The nurse set up the infusion with a 50 mg/50 mL morphine solution and set the pump rate at 2 mL/hour to deliver 2 mg/hour. The patient was also started on vasopressors for hypotension. One hour after starting the morphine, the nurse noted that the entire contents of the 50 mg bag of morphine solution had infused. During this time the patient required higher doses of vasopressors, which may have been related to the morphine overdose. The patient had been intubated and fully ventilated prior to initiation of the morphine infusion and thus neither respiratory arrest nor respiratory depression occurred.

The causes of these separate mishaps were not determined until the biomedical, management and front-line staff of one of the reporting hospitals conducted in-depth investigations. It was discovered that tubing loaded in a “curved” manner caused over-infusion and did not activate an alarm (see Figure 1). They also reported that both no flow and under-infusion could occur without an alarm if the loaded tubing became kinked or pinched (see Figure 2). ISMP Canada has since replicated all these “no alarm” scenarios with the 6201 model of the Baxter Flo Gard pump. (Model 6201 is the single channel and model 6301 is the dual channel version of the Flo Gard pump. These two models have identical pumping mechanisms.)

The infusion rate of most intravenous pumps is determined by a theoretical calculation that is determined by the rate of the pump motor rotation and the diameter of the intravenous tubing. It is not based on a measured calculation. Thus, in

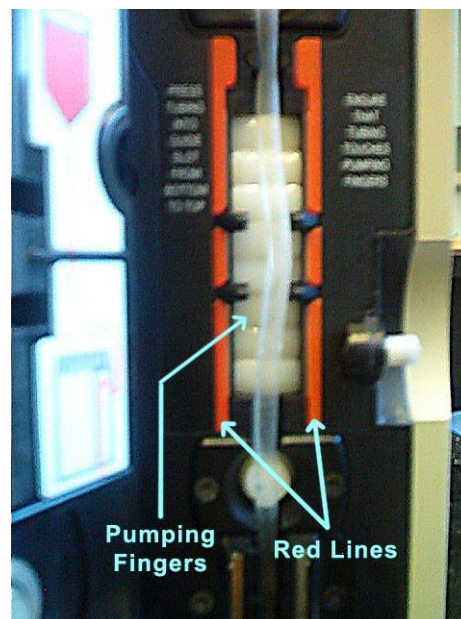


Figure 1. Over-infusion replicated.

Tubing incorrectly loaded in curved manner between red lines did not activate pump alarm.



Figure 2. No flow replicated.

Tubing pinched against triangular pieces when door was closed did not activate alarm.

ISMP Canada Safety Bulletin

order for an infusion pump to deliver the amount of solution programmed, not only must the pump be in proper working order, but the tubing must also be loaded correctly. In the over-infusion scenario, the curved tubing created periods during which the pumping mechanism was not in direct contact with the tubing. It was only during these periods that fast rates could be visualized in the drip chamber. Despite the over-infusion, the pump continued to display the amount infused corresponding to the set infusion rate because it did not recognize any problems with the position of the tubing. Thus, it is imperative that the user follow the manufacturer's instructions to ensure that the tubing is loaded straight and lying against the pumping fingers to facilitate accuracy in the delivery of intravenous solutions.

A curve in the tubing can readily result if the user allows slack in the tubing when loading it into the pump. Once the pump door is closed, any slack in the tubing can cause the tubing to become curved, kinked or pinched. The user manual provided by the manufacturer indicates that an alarm with a "check set loading" message and no flow of infusion occurs if the tubing is not loaded correctly. Users rely on pumps to identify problem conditions and to activate an alarm. During replication of the reported incidents it was found that tubing incorrectly loaded in a variety of ways on or between the red lines (see Figures 1 and 2) did not activate an alarm and subsequently led to over-infusion or under-infusion. Ideally, infusion pump sensors will activate an alarm for all cases of incorrectly loaded tubing in order to prevent over-infusion or under-infusion. Furthermore, correct loading of tubing into a pump should be a forced function, not relying on the user's technique.

In January 2003, Baxter Canada issued a Safety Alert to Flo-Gard 6201 and 6301 customers informing them of the availability of a free service kit to help remind healthcare providers of the importance of proper IV set loading. One of the reporting hospitals using the Flo Gard pump requested that ISMP Canada share the issues with Canadian hospitals through our bulletin. ISMP Canada has communicated the recent concerns to Baxter Corporation, which has agreed to issue a warning letter and precautionary labels to their customers. In addition, ISMP Canada has contacted and reported the situation to Health Canada's Medical Devices Bureau. Health Canada has requested details from Baxter regarding this issue and any other reports of similar incidents and is working with Baxter to ensure that appropriate action is taken.

ISMP Canada recommends that those hospitals using Baxter Flo Gard models 6201 and 6301 consider implementing the following safeguards:

- Educate all healthcare staff using these pumps that there may be a "no alarm" condition with improperly loaded tubing.
- Retrain all healthcare staff on the proper loading of the tubing according to instructions provided in the pump user manual, as well as the manufacturer's updates and labels. Emphasize the risks associated with incorrectly loaded tubing.
- Address this issue in all pump training sessions provided to new staff during orientation (including anaesthesiologists).
- Place brightly coloured, laminated labels on the pumps, with the warning of the possibility of no alarm with incorrectly loaded tubing.
- If using this pump for the delivery of high alert medications, consider additional safeguards that would be feasible for your organization after performing a Failure Mode and Effect Analysis (FMEA). Safeguards may include an independent double check on loading of tubing, the use of a buretrol with these pumps (with a specified volume limit, related to the drip rate in the volume control chamber) or another method that would create redundancy. A list of high alert medications can be found on the ISMP website:
www.ismp.org/msaarticles/highalertmedications.htm.

In addition, ISMP Canada continues to emphasize the importance of IV set loading according to the manufacturer's instruction for all makes of infusion pumps. Infusion pump problems should be reported to the manufacturer and to the Health Canada Hotline for medical device problem reporting (1-800-267-9675). Problems related to specific infusion pumps can also be reported to the U.S. Food and Drug Administration (FDA) and can be found on their website:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm. Reports shared with ISMP Canada are kept confidential and can be submitted on-line through the web site (www.ismp-canada.org), by e-mail (info@ismp-canada.org) or by phone (416-480-4099).

ISMP Canada thanks and acknowledges those who reported these infusion pump incidents, as well as Health Canada and Baxter Corporation for their ongoing commitment to bringing these issues to resolution.

©2003 Institute for Safe Medication Practices Canada. Permission is granted to subscribers to use material from ISMP Canada Safety Bulletin for in-house newsletters or other internal communications only. Reproduction by any other process prohibited without permission from ISMP Canada in writing.

ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

To report a medication error to ISMP Canada: (i) visit our website www.ismp-canada.org or (ii) email us at info@ismp-canada.org or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.