# Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences: FDA Safety Communication



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## Audience:

- **Health care professionals who use or who train users on programmable syringe pumps**
- **Health care professionals responsible for maintaining programmable syringe pumps**
- **Health care professionals who are responsible for how drugs are mixed for use in programmable syringe pumps**

## Specialties:

Nurses, nurse practitioners, certified registered nurse anesthetists, physician assistants, and physicians who interact with programmable syringe pumps or administer high risk and life-sustaining medication therapies, such as those who work in neonatal and pediatric intensive care or critical care units, labor and delivery units, operating rooms, and emergency departments. In addition, pharmacists who are responsible for mixing high risk and life-sustaining medications used in syringe pumps, and clinical or biomedical engineers responsible for maintenance or those who assist with syringe pump selection.

## Device:

Programmable syringe pumps deliver solutions such as fluids, medications, or blood products to patients. They are capable of delivering at low infusion rates in increments as small as tenths or hundredths of a milliliter per hour, and programming capabilities can include intermittent, fixed-volume, constant-rate infusions, and, particularly with critically-ill patients, continuous infusions subject to frequent adjustment or titration, as needed. They are commonly used in settings where patients may need highly

concentrated medication doses because of fluid restriction or fluid intolerance, such as neonatal intensive care units. Accessory devices used with programmable syringe pumps include a syringe that holds the solution, and infusion tubing that connects the syringe to the patient through intravenous or enteral access.

## Purpose:

The FDA is informing health care professionals that when using programmable syringe pumps to infuse therapies at low rates (e.g., less than 5 mL per hour, and especially at flow rates of less than 0.5 mL per hour), a lack of flow continuity (i.e., inconsistent rate of delivery) can result in serious clinical consequences, including delay of therapy, over-infusion or under-infusion. Reports of serious adverse events such as abnormal or unstable blood pressure, anxiety from loss of sedation, and increased pain indicators in critically-ill infants have been associated with lack of flow continuity. The FDA believes that these concerns may extend to all programmable syringe pumps while infusing at low rates. Based on current information, the FDA believes that the overall benefits of programmable syringe pumps outweigh their risks. Moving forward, the FDA has requested that manufacturers make labeling changes to their syringe pumps to address flow continuity concerns .

## Summary of Problem and Scope:

While lack of flow continuity can occur with other types of infusion pumps, this issue is particularly relevant to programmable syringe pumps that infuse therapies at low rates. Programmable syringe pumps can provide accurate delivery of fluids and medications over a wide range of infusion rates, including rates less than 5 mL per hour. In general, the lower the infusion rate, the higher the potential for problems to occur when certain techniques and/or accessory devices are used.

Problems with flow continuity while infusing at low rates may occur with programmable syringe pumps resulting in delay of therapy, over-infusion or under-infusion, and is not specific to any manufacturer or model of device. Intravenous delivery of fluids and medications must be accurately and precisely controlled in fluid restricted or fluid intolerant patients because the infusion rates are so low that even small changes in flow continuity can result in large deviations in the administered dose. For example, if medications are being infused to increase or decrease heart rate and/or blood pressure (vasoactive drugs), lack of flow continuity may lead to problems such as unstable heart rate and/or blood pressure (hemodynamic instability).

From March 01, 2013 to July 20, 2016, the FDA received over 300 Medical Device Reports (MDRs) associated with programmable syringe pump use. The reports describe over- and under- infusion of high risk or life-sustaining medications, occlusion (blockage) detection failures, inadvertent boluses caused by inconsistent fluid delivery, and other mechanical malfunctions that result in delays in therapy. Of the 100 MDRs that provided information on the infusion rates, the majority of those

MDRs noted infusions at rates of 5 mL per hour or less, including rates as low as 0.06 mL per hour.

Due to the limited information provided in these reports and the likely presence of significant comorbidities, it is often unclear if a correlation exists between the programmable syringe pump and patient outcome. MDRs are not, by themselves, definitive evidence of a faulty or defective medical device, and cannot be used to establish or compare rates of event occurrence. Therefore, the FDA obtained and evaluated other relevant information besides MDRs, including medical literature and user facility surveys to further evaluate these issues.

The FDA completed a small sample of MedSun surveys at hospitals, and found that clinical practice varies, including in syringe size selection, priming practices, and use of other accessory devices. It may be difficult for clinicians to associate problems with lack of flow continuity at low infusion rates to the syringe pump; these problems may be attributed to other patient conditions as the populations most at risk are likely very ill.

## Recommendations for Health Care Professionals:

Based on current information, the FDA believes the benefits of these devices outweigh their risks. The FDA recommends that health care professionals consider the following information when using programmable syringe pumps to help reduce the potential for serious adverse events:

### Syringe Size and Selection

- Ensure syringe sizes and models are compatible with the syringe pump (refer to the manufacturer's instructions for use). Use of incompatible syringes can cause improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, and other potential problems.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion detection alarms. This is due to the increased friction and variable compliance of the syringe plunger tip with larger syringes.

### Use of Accessory Devices

- Use manufacturer-identified compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates. This reduces the amount of time it takes for fluid to reach the patient, maintains delivery

accuracy, and reduces occlusion detection times. For example:

- **Tubing internal diameter:** Small bore or microbore tubing is recommended when infusing at low rates
- **Tubing length:** Tubing length should be minimized, when possible
- **Filters:** Internal volume (deadspace) of in-line filters should be minimized
- **Connection sites:** The number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the intravenous access site as possible.

- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g., 50-200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates.

## Starting an Infusion or Changing a Syringe

- Manually prime the syringe and tubing to remove all air, before connecting to the pump.
- **When available, electronically prime the syringe pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe.**
  - Verify the fluid flow to the patient is OFF and, if available, use the prime (or purge) function on the syringe pump to remove any mechanical slack in the system.
  - Using the syringe pump's prime (or purge) feature engages the mechanical components of the pump and decreases the syringe's friction and compliance (i.e., stiffness) to minimize startup delays and delivery inaccuracies, especially at low infusion rates.
  - Failure to use the prime (or purge) feature on the syringe pump (if available) after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.
- During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.

## Height and Location of the Syringe Pump System

- Ideally, the syringe pump should be level with the distal tip of the catheter (e.g., the site of fluid delivery; if accessing a central line the syringe pump should be at the level of the patient's heart). If the pump height is raised relative to the distal tip of the catheter (e.g., during patient transport), the increase in height of the syringe pump can result in a temporary increase in fluid delivery or bolus until the flow rate

stabilizes. Alternatively, if the pump is lowered relative to the distal tip of the catheter, the decrease in height of the syringe pump may result in a decrease in fluid delivery or under-infusion until the flow rate stabilizes.

- If multiple syringe pumps are utilized and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level with the distal tip of the catheter as possible.
- Minimize the height difference between the syringe pump and the patient and avoid changes in the height of the pump (e.g., during transport of critically-ill patients) to prevent unintended fluctuations in the flow rate.

## Occlusion Considerations

- To minimize the amount of time it takes the syringe pump to recognize an occlusion (blockage) and generate an alarm while infusing at low rates:
  - Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the plunger force or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g., lipids), the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms. For further information, refer to the manufacturer's instructions for use or contact the manufacturer, or speak with the biomedical engineering department in your facility.
  - Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e., stiffness) of the syringe plunger tip. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
  - If available, use the prime (or purge) feature on the syringe pump when changing a syringe and/or tubing.
  - Use accessory devices, which have the smallest internal volume or deadspace (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.).
- When addressing or clearing an occlusion:
  - **Ensure the fluid flow to the patient is OFF** to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing, or relieve the excess pressure through a stopcock, if present. The health care professional

should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

- Be aware that using larger size syringes on a high plunger force or occlusion setting may produce a larger post occlusion bolus due to excessive syringe plunger tip compliance.

For additional risk reduction recommendations, please refer to the FDA'sInfusion Pump Risk Reduction Strategies.

## FDA Activities:

The FDA has collected and analyzed data from MDRs, labeling, medical literature, and information from clinicians and manufacturers. The FDA has determined that lack of flow continuity while infusing at low rates may extend to all programmable syringe pumps capable of delivering at low infusion rates.

After reviewing additional information on this subject, the FDA asked manufacturers to voluntarily update their labeling, and sent a labeling change request letter to programmable syringe pump manufacturers currently on the market. The letter requested that manufacturers review their current labeling and include additional warnings, precautions, and other statements, consistent with the recommendations in this communication, to further clarify the use of these devices at low infusion rates. The FDA will work with the manufacturers to ensure the appropriate information is conveyed to health care providers and patients.

## Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a programmable syringe pump is having problems with flow continuity at low infusion rates, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

## Other Resources:

ECRI Institute. Syringe Pumps- Delay in Drug Delivery May Occur at Low Flow Rates, Putting Patients at Risk. *Medical Device Hazard Report*. 2015 October 6.

FDA's Infusion Pump Risk Reduction Strategies

MedSun survey

Peterfreund RA, Philip JH. Critical parameters in drug delivery by intravenous infusion. *Expert Opin Drug Deliv.* 2013; 10(8): 1095-1108.

Programmable syringe pump labeling change request letter to industry

Sherwin CMT, Medlicott NJ, Reith DM, Broadbent RS, Intravenous drug delivery in neonates: lessons learnt. *Archives of Disease in Childhood,* 2014; 99(6): 590–594.

Van der Eijk AC, van Rens R, Dankelman J, Smit BJ, A literature review on flow-rate variability in neonatal IV therapy. *Pediatric Anesthesia,* 2013; 23(1): 9-21.

## Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

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