

Infusion Pump Improvement Initiative

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Executive Summary

External infusion pumps (hereinafter “infusion pumps”) are medical devices that deliver fluids, including nutrients and medications, into a patient’s body in a controlled manner.¹ These devices are used worldwide in healthcare facilities, as well as in the home. Infusion pumps have contributed to improvements in patient care, allowing for a greater level of control, accuracy, and precision in drug delivery, and thereby reducing medication errors.

At the same time, like other medical devices, infusion pumps are not without risks. FDA has received numerous reports of adverse events associated with the use of infusion pumps, including serious injuries and deaths. From 2005 through 2009, 87 infusion pump recalls were conducted by firms to address identified safety problems.

Infusion pump problems have been observed across multiple manufacturers and pump types. Through analysis of pump-related adverse event reports and device recalls, FDA has concluded that many of these problems appear to be related to deficiencies in device design and engineering.

Taking a balanced public health approach, FDA seeks to support the benefits of infusion pumps while minimizing the risks. To date, FDA has largely responded to infusion pump failures on a case-by-case basis; however, this strategy has not been adequate, and problems persist.

This document announces the launch of FDA’s *Infusion Pump Improvement Initiative*. Through this initiative, FDA will take broad steps to prevent infusion pump problems:

1. Establish additional requirements for infusion pump manufacturers;
2. Proactively facilitate device improvements; and
3. Increase user awareness.

These comprehensive actions will foster the development of safer, more effective infusion pumps, and support the safe use of these vital medical devices.

Background

An infusion pump is a medical device that delivers fluids, such as nutrients and medications, into a patient’s body in controlled amounts. Infusion pumps are in widespread use in clinical settings such as hospitals, and in the home.²

In general, an infusion pump is operated by a trained user, who programs the rate and duration of fluid delivery through a built-in software interface. Infusion pumps offer significant advantages over manual administration of fluids, including the ability to deliver fluids in very small volumes, and the ability to deliver fluids at precisely programmed rates or automated intervals.

¹ This document does not pertain to implanted infusion pumps, which are surgically placed in the body.

² According to market research data, there was an estimated installed base of over two million external infusion pumps in U.S. hospitals and other healthcare settings in 2006. (Medtech Insight, “U.S. Markets for Drug and Fluid Delivery Devices,” October 2007.)

1. Types and Uses of Infusion Pumps

There are many different types of infusion pumps, which are used for a variety of purposes and in a variety of environments. Infusion pumps may be capable of administering fluids in large or small volumes, and may be used to deliver nutrients or medications, such as insulin or other hormones, antibiotics, chemotherapy drugs, and pain relievers. Some infusion pumps are designed mainly for stationary use at a patient's bedside. Others, called *ambulatory* infusion pumps, are designed to be portable or wearable.

There are a number of commonly used specialty infusion pumps, including *enteral*, *patient-controlled analgesia (PCA)*, and *insulin* infusion pumps. Enteral infusion pumps are used to deliver liquid nutrients and medications to a patient's digestive tract. PCA infusion pumps are used to deliver pain medication, and are equipped with a feature that allows patients to self-administer a controlled amount of medication, as needed. Insulin infusion pumps are typically used to deliver insulin to patients with diabetes, and are frequently used in the home.

Different types of infusion pumps have different fluid-control mechanisms, which may be powered electrically or mechanically. In a *syringe* infusion pump, for example, fluid is held in the reservoir of a syringe, and a moveable piston controls fluid delivery. In an *elastomeric* infusion pump, fluid is held in a stretchable balloon reservoir, and pressure from the elastic walls of the balloon drives fluid delivery. In a *peristaltic* pump, a set of rollers pinches down on a length of flexible tubing, pushing fluid forward. Some complex infusion pumps are capable of delivering fluids from multiple reservoirs at multiple rates.

Because infusion pumps are frequently used to administer critical fluids, including high-risk medications, pump failures can have significant implications for patient safety. Many infusion pumps are equipped with safety features, such as alarms or other operator alerts that are intended to activate in the event of a problem. For example, some pumps are designed to alert users when air or another blockage is detected in the tubing that delivers fluid to the patient. Some newer infusion pumps, often called *smart pumps*, are designed to alert the user when there is a risk of an adverse drug interaction, or when the user sets the pump's parameters outside of specified safety limits.

2. Causes for Concern

Over the past several years, significant safety issues related to infusion pumps have come to FDA's attention.

From 2005 through 2009, FDA received approximately 56,000 reports of adverse events associated with the use of infusion pumps, including numerous injuries and deaths. During this time period, 87 infusion pump recalls were conducted by firms to address identified safety concerns. 70 of these recalls were designated as Class II, a category that applies when the use of the recalled device may cause temporary or medically reversible adverse health consequences, or when the probability of serious adverse health consequences is remote. 14 recalls were Class I – situations in which there is a reasonable probability that use of the recalled device will cause serious adverse health consequences or death. These adverse event reports and device recalls have not been isolated to a specific manufacturer, type of infusion pump, or use environment; rather, they have occurred across the board.

Although some adverse events may be the result of user error, many of the reported events are related to deficiencies in device design and engineering, which can either create problems

themselves or contribute to user error. The most common types of reported problems have been associated with software defects, user interface issues, and mechanical or electrical failures. Examples of these types of problems are provided below. These examples are illustrative only and are not intended to capture all of the adverse events that have been reported to FDA.

Software Defects. Many of the problems that have been reported are related to software malfunctions. For example, some pumps fail to activate pre-programmed alarms when problems occur, while others activate an alarm in the absence of a problem. Other software errors can lead to over- or under-infusion. In one case, a software problem called a “key bounce” caused an infusion pump to occasionally register one keystroke (e.g., a single zero, “0”) as multiple keystrokes (e.g., a double zero, “00”).

User Interface Issues. There have also been numerous reports of confusing or unclear on-screen user instructions, which may lead to improper programming of medication doses or infusion rates. For example, the design of the infusion pump screen may not make clear which units of measurement (e.g., pounds versus kilograms) should be used to enter patient data, leading to inappropriate dosing.

Mechanical or Electrical Failures. Other problems that have been reported include components, such as pump housings, that break under routine use; premature battery failures; and sparks or pump fires. Each of these types of incidents can create risks to patients, including the potential for over- or under-administration of critical fluids.

Infusion Pump Improvement Initiative

FDA is launching the *Infusion Pump Improvement Initiative* to address infusion pump safety problems.

Infusion pump problems have been observed across multiple manufacturers, pump types, and use environments. FDA believes that better infusion pump design and engineering could prevent recurrence of many of the problems that have been observed. To date, FDA has taken actions to respond to issues that have arisen on a largely case-by-case basis; however, many of the same problems continue to occur. Through its new initiative, FDA is taking a more proactive and comprehensive approach to prevent safety problems by fostering the development of safer, more effective infusion pumps across the industry.

1. Establish Additional Requirements for Infusion Pump Manufacturers

In order to provide greater assurance that design deficiencies are identified and corrected before they lead to safety problems, FDA is moving to require that manufacturers of infusion pumps include additional design and engineering information as part of their premarket submissions and conduct additional testing of their devices.

As a first step, FDA is issuing and requesting public comment on a new, total product life cycle (TPLC) draft guidance document for infusion pump manufacturers.³ The draft guidance

³ The draft guidance, “Total Product Life Cycle: Infusion Pump Premarket Notification [510(k)] Submissions,” is available online at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm>.

recommends that manufacturers provide detailed design and engineering information to FDA during premarket review, and that each infusion pump premarket submission include a comprehensive discussion of steps the manufacturer has taken to mitigate risks at each stage of the device's life cycle – including design, manufacture, servicing and maintenance, and use. Further, the draft guidance recommends that manufacturers conduct design validation testing specific to the setting where the device is intended to be used (e.g., a hospital or the home), in order to account for real-life environmental or user interface issues.

The draft guidance also states that FDA may, in certain circumstances, exercise its authority to withhold premarket clearance of an infusion pump until the manufacturer's facility has been inspected. Finally, in order to assure that infusion pump-related adverse events are reported to FDA and that proper actions are taken to prevent recurrence, the document emphasizes manufacturers' postmarket reporting requirements.

FDA is sending a letter to all infusion pump manufacturers, notifying them that they may need to conduct additional risk assessments to support premarket clearance of new or modified pumps, and encouraging them to meet with FDA early in the device development process to discuss their submissions.

In the coming months, FDA intends to take appropriate steps, including a public comment period, to convert the new draft guidance document into a special controls guidance and regulation. This regulatory change would require manufacturers of new and existing pumps to comply with the specified recommendations or a reasonable equivalent.

2. Proactively Facilitate Device Improvements

FDA is actively working with manufacturers, members of the academic community, and others to address identified infusion pump problems. The agency is also collaborating with its foreign regulatory counterparts to confront infusion pump safety issues. FDA is currently engaged in a number of cooperative efforts to facilitate the development of safer and more effective infusion pumps.

For example, FDA is using its in-house expertise to help prevent malfunctions in infusion pump software. FDA's software experts are proficient in static analysis of software code, which can help to identify programming errors. In its letter to infusion pump manufacturers, FDA is offering manufacturers the option of submitting the software code used in their infusion pumps for analysis by agency experts prior to premarket review of new or modified devices, in order to facilitate the early detection and correction of any design defects.

Additionally, FDA is involved in the development of model-based software engineering and verification methods. Through the Generic Infusion Pump project, an ongoing collaboration with outside researchers, FDA has helped to develop an open-source software safety model and reference specifications that infusion pump manufacturers can use or adapt to verify the software in their devices.⁴ FDA encourages others, including members of industry, to participate in this effort.

FDA intends to host a public workshop on May 25 and 26, 2010, to discuss the nature, scope, and impact of the infusion pump problems that have been observed; explain the steps FDA is taking to address these problems; and explore additional opportunities for FDA, industry,

⁴ More information about the Generic Infusion Pump project is available online at <http://rtg.cis.upenn.edu/gip.php3>.

members of the academic community, foreign regulatory authorities, and others to work together to foster the development of safer and more reliable infusion pumps.

3. Increase User Awareness

FDA recognizes the importance of providing patients and clinicians with information and strategies to mitigate the risks associated with the use of existing infusion pumps, even before new and improved devices are developed.

To that end, FDA is launching a new infusion pump website, which features basic information about infusion pumps and commonly seen problems.⁵ The site also describes actions that patients and professionals who interact with infusion pumps – including hospital staff and administrators, as well as home users – could take to help prevent safety problems. FDA encourages all users to report infusion pump problems, in order to help the agency develop a better understanding of the risk-benefit profile of these devices and take appropriate actions to enhance patient safety.

Conclusion

Infusion pumps are used in hospitals and other healthcare settings worldwide. Infusion pumps have contributed to significant improvements in patient care, but they are not without problems. Taking a balanced public health approach, FDA seeks to support the benefits infusion pumps can provide while reducing associated risks. Through the *Infusion Pump Improvement Initiative*, FDA will work to establish additional requirements for infusion pump manufacturers, proactively facilitate device improvements, and increase user awareness, in order to address infusion pump problems and support the safe use of these devices.

⁵ The new infusion pump website can be found at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm>.