Bio Medical Term Project

On

Infusion pump

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Abstract

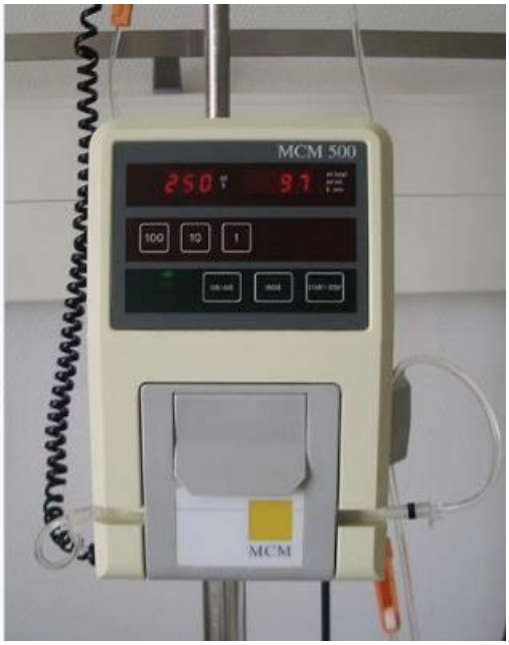
An infusion pump is a medical device that distributes controlled amounts of fluids, such as nutrients, into a patient's body. They're common in clinical environments like hospitals and nursing homes. Infusion pumps come in a variety of configurations, including large volume, patient-controlled analgesia, and insulin pumps. Because infusion pumps are regularly used to provide vital fluids, such as high-risk drugs, and pump failures can have serious consequences for a patient's safety, some are built primarily for stationary use at a patient's bedside. Approximately 56,000 reports of adverse events linked with the use of infusion pumps were received by the FDA between 2005 and 2009, including multiple injuries and deaths. Software issues, alarm mistakes, insufficient design, faulty components, battery failures, spark, and shock are just a few of the issues.

Introduction

A patient's circulatory system is infused with water, drugs, or nutrition using an infusion pump. Although subcutaneous, arterial, and epidural infusions are rarely utilized, it is mostly administered intravenously.

Infusion pumps can deliver fluids in ways that would be prohibitively expensive or unreliable if done by nurses manually. They can, for example, administer injections as small as 0.1 mL per hour (too small for a drip), injections every minute, injections with repeated boluses requested by the patient, up to a maximum number per hour (e.g., in patient-controlled analgesia), or fluids whose volumes vary depending on the time of day.

They can inject regulated amounts of fluids subcutaneously (beneath the skin) or epidurally (just within the surface of the central nervous system – a highly common local spinal anaesthetic for childbirth) since they can produce quite high but controlled pressures.



Types of Infusion pump manufactured by Fresenius

- **Types and uses of infusion pump**

Infusion pumps come in a range of shapes and sizes, and they're utilised for a number of purposes and in a variety of settings. Infusion pumps can give large or tiny amounts of fluid and can be used to deliver nutrition or pharmaceuticals like insulin or other hormones, antibiotics, chemotherapeutic treatments, and pain relievers. Some infusion pumps are intended for usage at the patient's bedside only. Ambulatory infusion pumps, for example, are designed to be portable or wearable.

Enteral, patient-controlled analgesia (PCA), and insulin infusion pumps are among the most often utilised specialty infusion pumps. Enteral infusion pumps administer liquid nutrients and drugs to a patient's gastrointestinal system. Pain medicine is delivered via PCA infusion pumps, which have a feature that allows patients to self-administer a controlled dose of medication as needed. Insulin infusion pumps are used to give insulin to diabetic patients and are commonly used in the home.

Fluid-control techniques vary by kind of infusion pump, and they can be powered electrically or mechanically. Fluid is retained in the reservoir of a syringe in a syringe infusion pump, for

example, and fluid distribution is controlled by a moving piston. Fluid is kept in a flexible balloon reservoir in an elastomeric infusion pump, and pressure from the balloon's elastic walls drives fluid delivery. A set of rollers pinches down on a length of flexible tubing in a peristaltic pump, pushing fluid ahead. Some sophisticated infusion pumps can distribute fluids from numerous reservoirs at different speeds.

Pump failures can have serious consequences for patient safety because infusion pumps are regularly used to give vital fluids, including high-risk drugs. Many infusion pumps have safety features, such as alarms or other operator alerts, that are supposed to go off if something goes wrong. Some pumps, for example, are programmed to notify users if air or another blockage is detected in the tube delivering fluid to the patient. Some modern infusion pumps, dubbed "smart pumps," are designed to warn the user if there is a possibility of an unfavourable drug interaction or if the pump's parameters are adjusted outside of predefined safety limits.

- **Causes for concern**

Significant safety concerns about infusion pumps have been brought to FDA's attention in recent years.

Approximately 56,000 reports of adverse events linked with the use of infusion pumps were received by the FDA between 2005 and 2009, including multiple injuries and deaths. 87 infusion pump recalls were issued by companies during this time period to address safety issues. 70 of these recalls were classified as Class II, which means that the recalled equipment may produce transient or medically reversible adverse health effects, or that the risk of major adverse health consequences is low. There were 14 Class I recalls, which indicate that there is a reasonable chance that using the recalled device would result in significant health consequences or death. These adverse event reports and device recalls aren't limited to a single manufacturer or product category.

Although some bad occurrences may be due to human mistake, many of the recorded incidents are linked to flaws in device design and engineering, which can either cause

problems or contribute to them. Software faults, user interface issues, and mechanical or electrical failures have all been linked to the most common types of reported issues. Below are some examples of these types of issues. These are only a few examples; they aren't meant to represent all of the adverse events that have been reported to the FDA.

Software defects. Many of the issues that have been reported have to do with software issues. Some pumps, for example, fail to activate pre-programmed alerts when difficulties occur, while others do so even when there isn't a problem. Over- or under-infusion can be caused by other software faults. In one example, a software issue known as "key bounce" caused an infusion pump to periodically register a single keystroke (e.g., "0") as numerous keystrokes (e.g., "00").

User interface issue. There have also been multiple reports of unclear or confusing on-screen user instructions, which could lead to incorrect medicine doses or infusion rates being programmed. The infusion pump screen, for example, may not make it apparent which units of measurement (e.g., pounds versus kilogrammes) should be used to enter patient data, resulting in incorrect dosing.

Mechanical and electrical failures. Components, such as pump housings, that break under normal usage have also been recorded, as have premature battery failures, sparks, and pump fires. Each of these occurrences poses a risk to patients, including the possibility of vital fluids being administered excessively or insufficiently.

Infusion Pump Improvement Initiative

To address infusion pump safety issues, the FDA has launched the Infusion Pump Improvement Initiative.

Problems with infusion pumps have been reported across a wide range of brands, pump types, and use conditions. Many of the problems that have been reported might be avoided with better infusion pump design and engineering, according to the FDA. To date, FDA has acted on a case-by-case basis to address difficulties that have occurred; nonetheless, many of the same issues continue to recur.

FDA's new effort encourages the development of safer, more effective infusion pumps across the industry, providing a more proactive and comprehensive approach to preventing safety issues.

- **Establish additional requirements for infusion pump manufactures**

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

As a preliminary step, FDA is releasing a draught total product life cycle (TPLC) guidance document for infusion pump manufacturers and inviting public comment. 3 Infusion pump premarket submissions should include a full assessment of efforts the manufacturer has taken to mitigate risks at each stage of the device's life cycle, including design, manufacture, servicing and maintenance, and use, according to the proposed advice. In addition, the draught advice suggests that manufacturers do design validation testing particular to the place in which the device will be used (e.g., a hospital or the home) to account for real-world environmental and user interface challenges.

The draught advice also notes that FDA may use its authority to withhold premarket approval of an infusion pump until the manufacturer's facility has been inspected in certain circumstances. Finally, the document highlights manufacturers' postmarket reporting requirements in order to ensure that infusion pump-related adverse events are reported to FDA and that appropriate actions are taken to prevent recurrence.

All infusion pump manufacturers will get a letter from FDA informing them that they may need to complete extra risk assessments to support premarket approval of new or modified pumps, and asking them to meet with FDA early in the device development process to discuss their submissions.

FDA plans to take the necessary processes, including a public comment period, in the coming months to transform the new draught guidance document into a special controls advice and

regulation. Manufacturers of new and existing pumps would be required to comply with the specified recommendations or a reasonable equivalent under this regulatory change.

- **Proactively facilitate device improvements**

The FDA is actively working with manufacturers, academics, and others to address infusion pump issues that have been reported. In order to address infusion pump safety concerns, the FDA is engaging with its overseas regulatory colleagues. The FDA is actively working on a variety of collaborative projects to help develop safer and more effective infusion pumps.

For example, FDA is utilising its in-house expertise to assist in the prevention of infusion pump software problems. Static analysis of software code is a skill that FDA software specialists have, and it can help discover programming mistakes. FDA is offering infusion pump manufacturers the option of submitting the software code used in their 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, according to a letter sent to infusion pump manufacturers.

In addition, the FDA is working on developing model-based software engineering and verification approaches. FDA has contributed to the development of an open-source software safety model and reference requirements that infusion pump manufacturers can use or change to validate the software in their devices through the Generic Infusion Pump project, an ongoing partnership with independent researchers. 4 Others, especially members of the industry, are encouraged to join in this effort.

On May 25 and 26, 2010, FDA plans to hold a public workshop to discuss the nature, scope, and impact of the infusion pump problems that have been reported, as well as to explain the steps FDA is taking to address these issues and to explore additional opportunities for FDA, industry, academics, foreign regulatory authorities, and others to collaborate to develop safer and more reliable infusion pumps.

- **Increase user awareness**

Even before new and improved devices are created, the FDA acknowledges the need of providing patients and clinicians with information and techniques to limit the hazards associated with the use of existing infusion pumps.

To that purpose, the FDA is creating a new infusion pump website, which will provide basic information on infusion pumps as well as typical issues. 5 Patients and professionals who engage with infusion pumps, such as hospital staff and administrators, as well as home users, can take steps to assist prevent safety issues, according to the website. The FDA encourages all infusion pump users to report concerns so that the agency can better understand the risk-benefit profile of these devices and take appropriate steps to improve patient safety.

Conclusion

Infusion pumps are widely utilised in hospitals and other healthcare facilities around the world. Infusion pumps have helped to improve patient care significantly, yet they are not without flaws. FDA wants to support the benefits infusion pumps can provide while decreasing associated hazards, using a balanced public health approach. In order to address infusion pump concerns and support the safe use of these devices, FDA will strive to set additional requirements for infusion pump manufacturers, proactively facilitate device improvements, and increase user knowledge through the Infusion Pump Improvement Initiative.

Reference:

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