

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. The most common types of reported problems have been associated with software defects, user interface issues, and mechanical or electrical failures and are explained on the Examples of Reported Infusion Pump Problems page. 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. There are many types of infusion pumps, including large volume, patient-controlled analgesia (PCA), elastomeric, syringe, enteral, and insulin pumps. Seventy 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. Because infusion pumps are frequently used to administer critical fluids, including high-risk medications, pump failures can have significant implications for patient safety. 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. 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. Others, called ambulatory infusion pumps, are designed to be portable or wearable.