The Bioscan
AN INTERNATIONAL QUARTERLY JOURNAL OF LIFE SCIENCES
20(3): S.I (3), 1256-1264, 2025 www.thebioscan.com

DEVICE FAILURES AND COMPLIANCE GAPS IN INFUSION PUMPS: RETROSPECTIVE TRENDS FROM FDA AND MEDSUN REPORTS.

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DOI: 10.63001/tbs.2025.v20.i03.S.I(3).pp1256-1264

KEYWORDS
Infusion pumps, recalls, Adverse events, CAPA.

Received on:

04-08-2025

Accepted on:

08-09-2025

Published on:

07-10-2025

ABSTRACT

This study conducted a retrospective data analysis and structured literature review to examine the safety, malfunction trends, and regulatory actions concerning infusion pumps from 2022 to 2024, utilizing data from the FDA Product Classification database, MEDSUN, and FDA Recalls. A total of 580 adverse event causes were reported, with the FRN (general-purpose infusion pump) model accounting for nearly 79% of these events, and potential patient harm cited in 46.6% of all incidents. Analysis of device issues revealed pump malfunctions as the most frequent problem (approximately 145 cases), followed by inaccurate infusion rates (around 65 cases) and alarm malfunctions (approximately 60 cases); the FRN device consistently contributed the most to all malfunction types, including 91.7% of alarm malfunctions and 85.7% of battery issues. Infusion pump recalls significantly increased, from 28 in 2022 to 55 in 2024, with the FRN model implicated in most recalls, including 15 Class I recalls in both 2023 and 2024. Observed regulatory compliance gaps, such as inadequate design validation, ineffective Corrective and Preventive Actions (CAPA) for recurring issues, and insufficient human factors engineering, underscore the critical need for targeted CAPA measures and enhanced regulatory oversight, particularly for the FRN model, to improve the overall safety and reliability of infusion pump technologies.

INTRODUCTION

Infusion pumps are medical devices designed to deliver fluids, such as nutrients or medications into a patient's body in a controlled manner. The term external infusion pump generally refers to devices that operate outside the body and deliver fluids through to the patient's circulatory system or other targeted site. This is to differentiate them from implantable infusion pumps, which are surgically placed inside the body and deliver medication directly to targeted sites such as the intrathecal space or hepatic artery(Sefton, 2019). As defined by the US Food and Drug Administration "An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm" (U. R. Kim et al., 2017).

2. RISK ASSOCIATED WITH INFUSION PUMPS:

Infusion pumps are very important in healthcare because they make sure that patients get the right amount of fluids, medications, or nutrients at the right time. Even though they have benefits, using them could be dangerous because of technical problems and user mistakes. Errors in medication are a big worry. Giving the medicine in the wrong amount, at the wrong rate, or with the wrong dose are some of these. Mistakes like these could lead to serious problems like drug toxicity, treatment failure, or fluid imbalance. These mistakes could lead to either an over-infusion or an under-infusion (Lyons & Blandford, 2018). Another common problem is choosing the wrong drug library or skipping it. Infusion pumps often use drug libraries that have preset parameters and safety limits. If the user picks the wrong medicine or dose or ignores warnings meant to help them avoid making mistakes, the patient could suffer bad effects. In addition to worries about medication, device malfunctions and technical problems add another layer of risk. These include software problems that could make the pump unsafe to use, such as bugs, glitches, or flaws in the operating system (Waterson et al., 2020). Alarm-related problems, like alarms not going off during important events or too many annoying alarms that make people tired of them, can make healthcare workers ignore or miss important warnings (Sowan et al., 2016). Mechanical problems, like damage to internal parts, can cause the pump to stop working or not work right. Blockages, or occlusions, in the IV site or infusion tubing can make it harder for the medication to reach the patient. When there are air bubbles in the tubing, this is called air-in-line, and it can cause air embolism. This also means that there is a chance of uncontrolled medication delivery (free flow) or unintentional reverse flow (backflow), flow that is not accurate

because of calibration problems, and battery failure during important therapy (Gao et al., 2019). As infusion pumps become more connected, cybersecurity holes have become a major threat because someone who isn't supposed to have access could change the pump settings and put patients in danger (Williams & Woodward, 2015).

Human factors and interface design also make risks much higher. If user interfaces are poorly designed, they can lead to programming errors. For example, screens that are hard to understand, units that are hard to understand, or navigation that is hard to follow. Not enough training or not knowing how to use a specific pump model or feature are common causes of misuse(Hersh et al. 2001) . In high-pressure clinical settings, staff members may make mistakes because they are interrupted or don't have enough time. Some users might also intentionally or unintentionally get around built-in safety features for the sake of convenience or lack of knowledge (Giuliano 2018). Last but not least, you should think about the environment. Other electronic devices can cause electromagnetic interference (EMI), which can stop infusion pumps from working. Very hot or cold temperatures can make performance worse. Even though most pumps have backup batteries, long power outages or batteries that aren't charged can stop important infusions and put patient care at risk (Spahić, Pokvić, and Badnjević 2024). In conclusion, infusion pumps are necessary for giving the right treatment, but they also come with a lot of risks. These include user mistakes, technical problems, medication mistakes, and things that happen in the environment. To lower these risks, it is important to strictly follow safety rules and keep making improvements to design, training, maintenance, and cybersecurity.

3. CLINICAL APPLICATIONS OF INFUSION PUMPS:

1. Continuous Intravenous (IV) Infusions: These pumps are vital for delivering drugs consistently over time to maintain a stable therapeutic level in a patient's bloodstream. This application is crucial for medications like antibiotics, chemotherapy drugs, pain management medications, vasopressors/inotropes (to support blood pressure and heart function), sedatives, and insulin. The continuous and controlled delivery minimizes fluctuations in drug concentration, leading to more predictable patient responses and improved outcomes .(Peterfreund & Philip, 2013).

2. Fluid Replacement/Hydration: Infusion pumps are extensively used for patients who cannot consume fluids orally, are severely dehydrated, or require continuous fluid support. This includes administering large volumes of saline or glucose solutions to rehydrate patients or maintain electrolyte balance, and carefully controlled infusions of blood products such as packed red blood cells, plasma, or platelets (Caccialanza et al. 2018)

3. Critical Care Settings: In environments where patients are critically ill and often require multiple, simultaneous, and precise infusions of life-sustaining medications, infusion pumps are indispensable. They are standard equipment in Intensive Care Units (ICUs), Emergency Rooms (ERs), and Operating Rooms (ORs)/Anesthesia settings, where minute-to-minute adjustments and accurate delivery of potent drugs are paramount to patient survival and stability.

4. Specialized Deliveries: Infusion pumps excel in situations where medications need to be delivered in extremely tiny volumes (e.g., 0.1 mL per hour), which would be impossible to manage manually. This is particularly important in:

- **Pediatric and Neonatal Care:** Where precise, small doses are critical for infants and children due to their sensitive physiology and low body weight.
- **Patient-Controlled Analgesia (PCA):** Allowing patients to self-administer small, on-demand doses of pain medication within pre-set safety limits, providing effective pain relief while minimizing overdose risk.
- **Epidural Infusions:** For continuous pain relief, especially during labor or post-operative recovery, where a steady, low dose of medication is delivered directly into the epidural space.
- **Subcutaneous Infusions**: For medications that can be absorbed through the fatty tissue under the skin, offering an alternative to IV administration for certain drugs, often used in palliative care or for specific hormonal therapies.
- **Nutritional Support (Parenteral Nutrition):** Delivering specialized liquid nutrition directly into a patient's bloodstream when they cannot digest food through their gastrointestinal tract. This complex mixture of carbohydrates, proteins, fats, vitamins, and minerals requires precise, slow infusion to prevent metabolic complications.
- **Chemotherapy Delivery:** Beyond continuous infusions, pumps are used for complex chemotherapy regimens that might involve specific infusion rates, boluses, or cyclical delivery patterns to maximize drug efficacy and manage side effects (Meng and Hoang 2012)

4. TYPES OF INFUSION PUMPS:

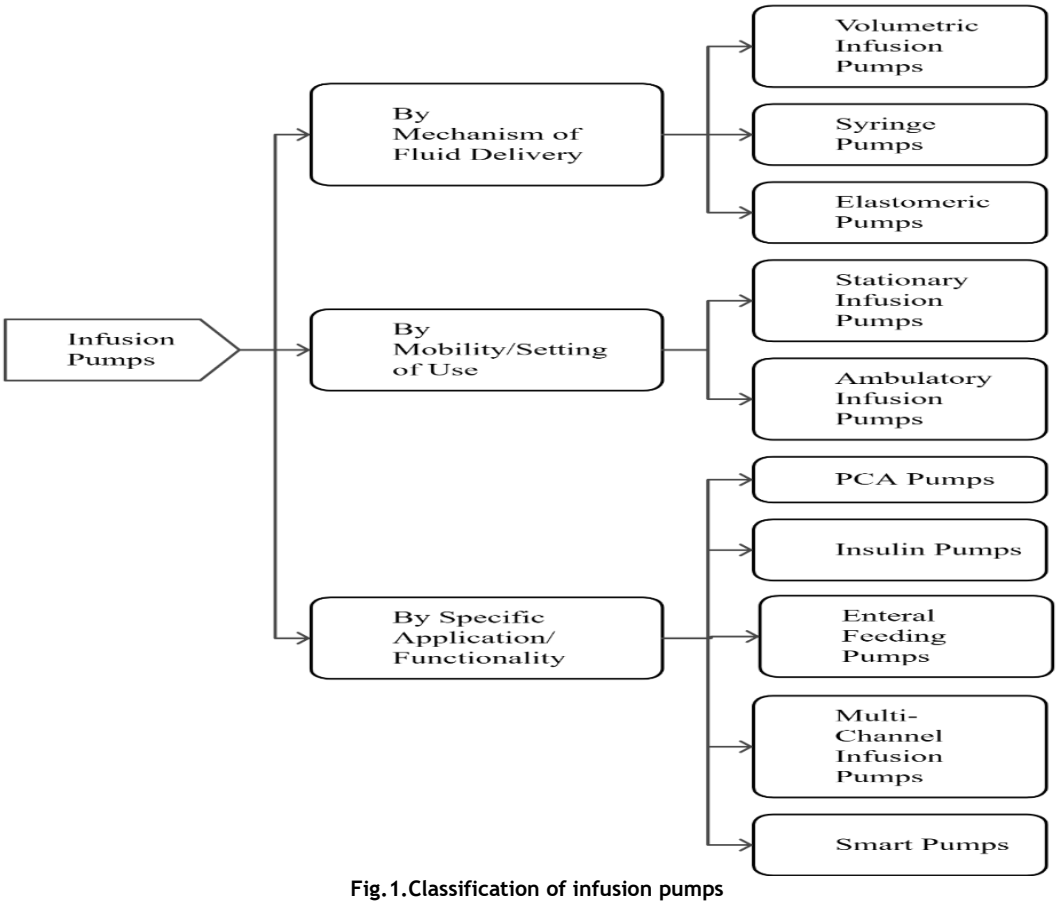


Fig.1.Classification of infusion pumps

5. RISK CLASSIFICATION OF INFUSION PUMPS

The FDA considers external infusion pumps to be Class II medical devices in the United States, which means they are moderately risky and need a 510(k) premarket notification. On the other hand, because of their important function and internal placement, implantable infusion pumps are regarded as Class III, the highest-risk category, and need strict Premarket Approval (PMA). Depending on their use and duration, external pumps are normally classified as Class IIa or IIb under the Medical Device Regulation (EU MDR) in the European Union, whereas implantable pumps are always classified as Class III due to their intrusive, long-term function. Comparably, the Central Drugs Standard Control Organization (CDSCO) in India assigns class C (moderate to high risk) to external infusion pumps and class D (highest risk) to implantable pumps, indicating the need for stringent regulatory oversight. Based on the complexity of the technology and its possible effects on patient health, these classifications aid in ensuring safety and efficacy (Rimpi et al. 2025)

Type of Infusion Pump	USA (FDA)	EU (MDR)	India (CDSCO)
External Infusion Pump	Class II (moderate risk)	Class IIb (moderate-high risk)	Class C (moderate-high risk)
Implantable Infusion Pump	Class III (high risk)	Class III (high risk)	Class D (high risk)

Table.1. Risk classification of Infusion pumps

6. FUTURE ADVANCES IN INFUSION PUMPS:

Future developments in infusion pumps are opening the door to healthcare that is safer, more individualized, and easier to access. The ability of pumps to modify drug flow by reading real-time patient data such as blood pressure or glucose levels through connected monitors is one significant advancement. This improves safety, minimizes manual adjustments, and eliminates guesswork especially for patients who need constant adjustments. Although these systems are already in use for the delivery of insulin, they are currently being investigated for a more responsive approach to infusion therapy in intensive care units and pain management settings. The development of 3D-printable infusion pumps, which enable adaptable, portable, and reasonably priced designs, is another significant innovation. To meet the needs of particular patients or to be used in places with limited resources, these pumps can be made from soft, flexible materials. They are perfect for emergencies, at-home care, and perhaps even future implantable applications due to their small size, light weight, and potential biodegradability (Gu et al. 2023). Furthermore, digital twin technology is becoming more popular because it provides a virtual model that replicates the pump's behavior in real time. Digital twins can improve safety, adjust infusion rates, and predict problems like start-up delays by combining sensor networks and AI. The transition to intelligent, data-driven systems improves the accuracy and adaptability of infusion therapy (Alamelu & Asaithambi, 2025). By preventing medication errors through the use of drug libraries and real-time alerts, Dose Error Reduction Software (DERS) is also making a significant impact. Future iterations of DERS might incorporate AI capabilities that suggest customized dosage, and its integration with barcode and electronic record systems greatly minimizes human error. Last but not least, despite being in use today, Electronic Medical Record (EMR) integration is still developing. While current systems primarily facilitate auto-documentation, fully synchronized pumps that automatically modify dosages, interface with other hospital systems, and support an intelligent, seamless care environment are the way of the future. The future of infusion technology is represented by these trends taken together, which will improve treatment efficiency, dependability, and customization (Xu et al., 2023).

7. REGULATORY MONITORING AND APPROVAL:

The Food and Drug Administration (FDA) oversees and regulates infusion pumps in the US Through its Center for Devices and Radiological Health (CDRH). The majority of infusion pumps fall under the category of Class II medical devices, which means they are moderately dangerous and need special precautions. Manufacturers of these devices must show that they are substantially equivalent to a legally marketed device in order to be allowed to enter the market through the 510(k) premarket notification pathway. Certain sophisticated or high-risk pumps

might fall under Class III, which calls for Premarket Approval (PMA), or they might be new but low-to-moderate risk, in which case they would go through the De Novo pathway. Infusion pumps are monitored after they are put on the market using tools like Medical Device Reporting (MDR), post-market studies, and recalls in case of safety concerns or malfunctions. In order to verify adherence to the Quality System Regulations (21 CFR Part 820), which address design controls, complaint resolution, and corrective actions, the FDA also regularly inspects manufacturing facilities (J. Kim et al., 2024). The FDA places a strong emphasis on human factors engineering and thorough software validation because many errors are caused by usability and software flaws, especially in smart pumps with digital features. To assist manufacturers in guaranteeing the safety and functionality of their devices, the agency also publishes guidance documents, such as the "Infusion Pumps Total Product Life Cycle Guidance." The FDA continues to assess software-integrated pumps in light of the growing importance of digital health through programs such as the Digital Health Software Precertification Program. This all-encompassing strategy guarantees that infusion pumps in the US are secure, efficient, and regularly inspected during their lifetime. The FDA approval procedures for external and implantable infusion pumps are shown in the flowchart below.

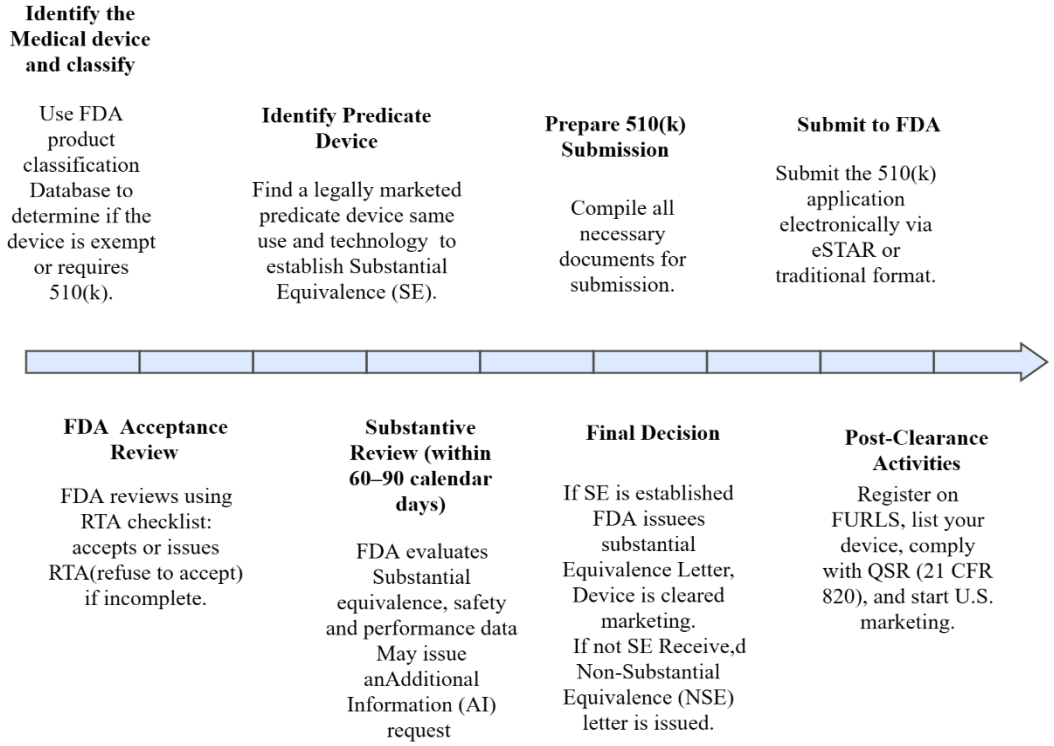


Fig:2 510(k) notification for class II external infusion pumps

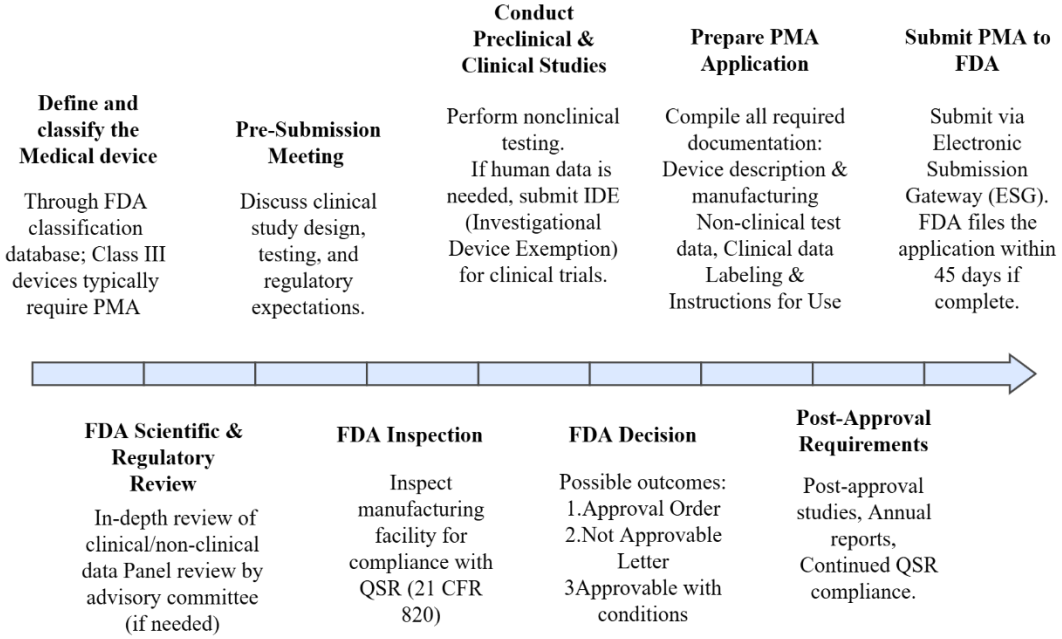


Fig 3: PMA for Class III Implantable infusion pumps

8. MEDSUN

MedSun continues to be a pillar of the FDA's post-market surveillance Operating through a network of more than 300 clinical sites, including hospitals, assisted living facilities, and outpatient clinics. These sites report adverse events involving medical devices using a secure online system. In close coordination with the FDA's Center for Devices and Radiological Health (CDRH), participants get immediate feedback on issues

that are reported and cooperate to look into and fix device-related issues. MedSun keeps interacting with subnetworks that are concentrated on high-risk clinical settings, like pediatric intensive care units, clinical labs, electrophysiology labs, and tissue/cell units, in order to improve data collection. This allows for the prompt identification and more thorough examination of device problems straight from frontline users. Under the program's two-way communication model, facilities report adverse events, the FDA works with them to investigate, and the results are disseminated widely to enhance safety procedures (Brown, Bright, and Tavris 2007; Shuren and Califf 2016). All reports are anonymized to protect the identities of those involved. These subnetworks' real-time monitoring offers continuous communication with the FDA and prompt, actionable feedback. Furthermore, MedSun facilitates educational and cooperative efforts by holding focus groups, webinars, and train-the-trainer courses that enable local employees to identify and effectively report device problems(Shuren and Califf 2016)

Product Code	Device Type	Risk Classification	Approval Pathway
FRN	General-Purpose Infusion Pump	Class II	510(k)
MEA	Patient Controlled Analgesia (PCA) Infusion Pump	Class II	510(k)
MEB	Elastomeric Infusion Pump	Class II	510(k)
LZG	Insulin Infusion Pump	Class II	510(k)
OPP	Insulin Bolus Infusion Pump	Class II	510(k)
LZH	Enteral Infusion Pump	Class II	510(k)
MRZ	Infusion Pump Accessories	Class II	510(k)
PHC	Infusion Safety Management Software	Class II	510(k)
LKK	Programmable Implantable Infusion Pump	Class III	PMA (Premarket Approval)

Table 2: Risk classification and approval pathways for infusion pumps (FDA)

8. METHODOLOGY

The current study investigated the safety, malfunction trends, and regulatory actions related to different types of infusion pumps using a structured literature review and retrospective data analysis. Data were collected in a planned way from publicly available databases, such as the FDA Product Classification database, the Medical Product Safety Network (MEDSUN), and the FDA Recalls (Enforcement Reports) database. To facilitate comparison of devices across categories, infusion pump devices were first grouped by their FDA product codes (for example, FRN for general-purpose infusion pumps, MEA for patient-controlled analgesia pumps, MEB for elastomeric pumps, LZG for insulin infusion pumps, and so on). Subsequently, MEDSUN's reports of types of adverse events and devices for the years 2022, 2023, and 2024 were examined. The focus was on device problems like pump malfunctions, alarm system failures, wrong infusion rates, battery problems, tubing problems, and software-related incidents. Concurrently, recall data for 2024, 2023, and 2022 were collected to analyze the number and types of recalls (Class I, II, III), the manufacturers and device brands involved, and the reasons for the recalls. The information was compiled and sorted by device type, event severity (such as death, serious injury, or possible harm to the patient), and frequency of occurrence. This method facilitated the identification of patterns in device performance and safety signals after commercialization. This study suggests Corrective and Preventive Action (CAPA) recommendations to the FDA based on the results. The goal is to improve the regulatory oversight and overall safety of infusion pump technologies used in clinical settings.

9.RESULTS AND DISCUSSION

9.1.TRENDS IN ADVERSE EVENT REPORTS FOR INFUSION PUMPS (2022-2024)

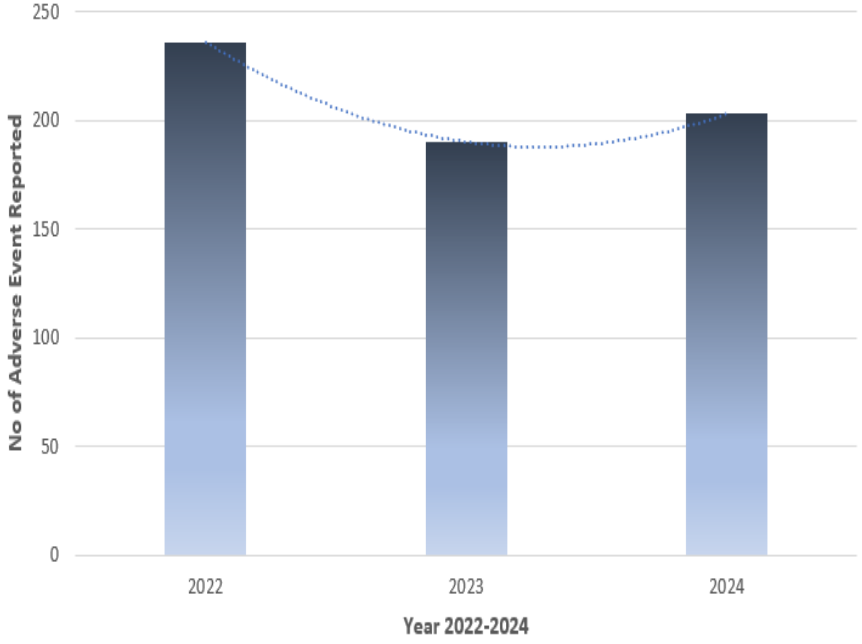


Fig 3: Adverse Event Reports for Infusion Pumps (2022-2024)

There were 236 infusion pump-related adverse events reported in 2022. With 190 events recorded in 2023, this number dropped by 19.5%. The number of reports rose to 203 in 2024, a 6.8% increase over the year before.

9.2. DEVICE SPECIFIC CAUSE DISTRIBUTION (2022-2024)

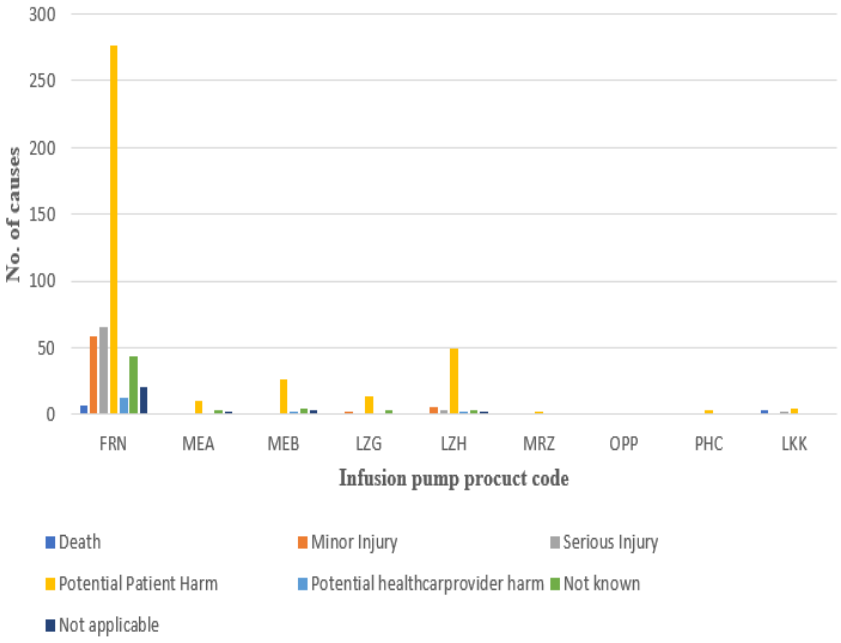


Fig 4: Cause Contribution of Infusion pumps (2022-2024)

A total of approximately 580 causes for adverse events linked to infusion pumps were reported for different product codes between 2022 and 2024. Potential patient harm accounted for 46.6% of all events, and the FRN infusion pump alone was responsible for almost 79% of all reported causes. Serious injury (8.6%), minor injury (7.8%), and healthcare provider harm (5.2%) were other significant harm categories associated with FRN. In comparison, the combined contribution of all other infusion pump types was only 13% of the total causes, with LZH coming in second only to FRN. This high volume of reports about the FRN device emphasizes how important it was to the general safety issues with infusion pumps at the time.

Adverse event reports for infusion pumps varied from 2022 to 2024, declining in 2023 and then increasing in 2024. This pattern is in line with device-specific data, which showed that the FRN pump alone was responsible for almost 79% of the approximately 580 causes that were reported. In addition to serious injury, minor injury, and healthcare provider harm—all of which were primarily connected to FRN—the majority of events (46.6%) involved possible patient harm. The small contribution from other devices (13%) emphasizes how much the safety performance of the FRN pump impacted the overall trend.

3. TYPES OF DEVICE ISSUES AND CONTRIBUTING FACTORS

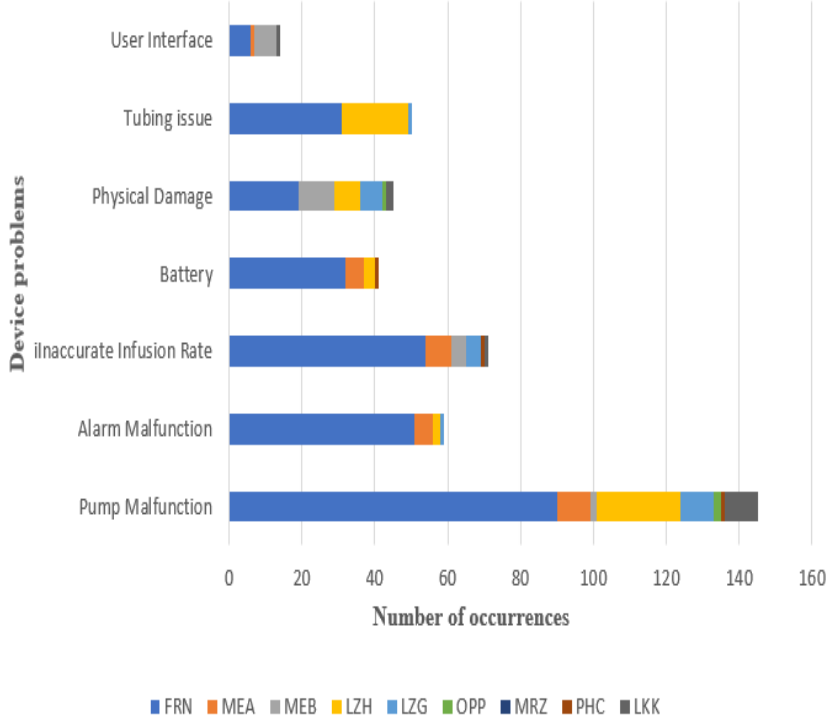


Fig 5: Reports of infusion pump device malfunctions categorized by FDA product code and issue type.

The frequency and device-wise contribution of device-related malfunctions from 2022 to 2024 are summarized in this chart. The most frequent problem (~145 cases) was pump malfunction, which was followed by inaccurate infusion rate (~65) and alarm malfunction (~60). The least frequent problem was user interface errors. Across all malfunction types, including 91.7% of alarm malfunctions, 85.7% of battery problems, and more than 60% of pump and tubing failures, the FRN device model continuously made the largest contribution. Pump malfunctions and tubing problems were also caused by devices such as MEA and LZH. These

patterns show that in order to increase device reliability and lower adverse events, CAPA measures centered on the FRN model must be implemented.

4. EVOLVING PATTERN OF DEVICE MALFUNCTIONS OVER THREE YEARS (2022-2024):

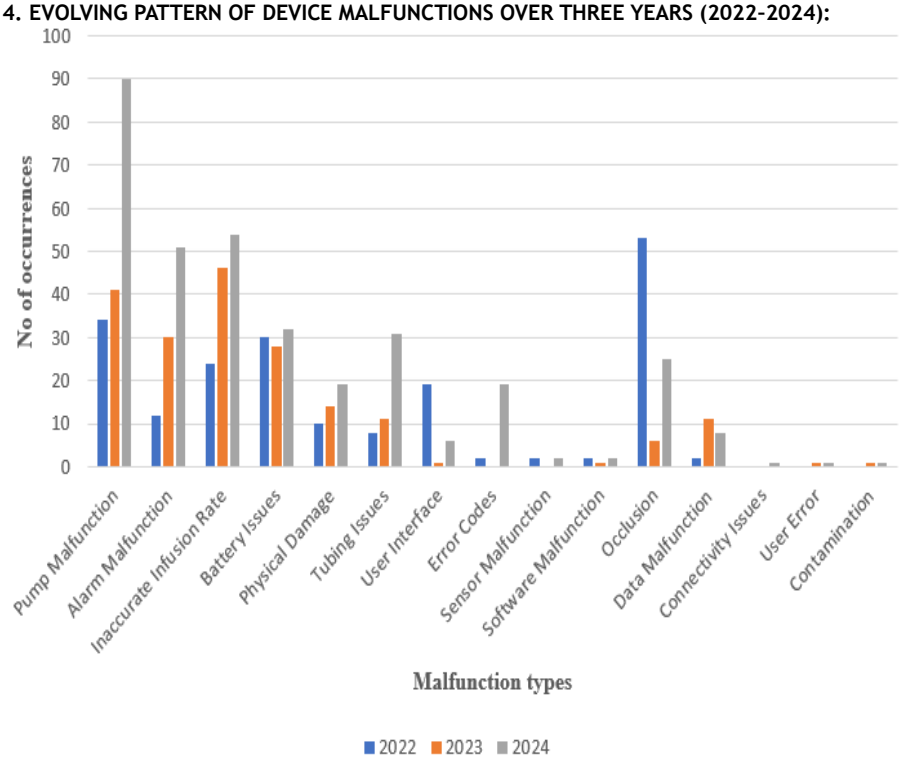
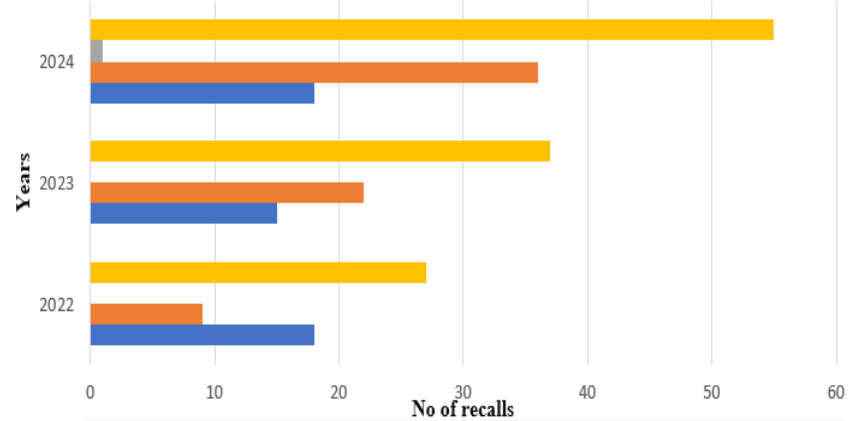


Fig 6: Reported Infusion Pump Malfunction Types (2022-2024)

Pump malfunction became the most common problem between 2022 and 2024, rising from 34 to 90 cases, suggesting ongoing performance issues. Alarm malfunction and the inaccurate infusion rate also increased gradually, reaching 54 and 51 cases in 2024, respectively. Notably, there were notable spikes in Tubing Issues and Error Codes, indicating possible software or design flaws. Variations in Occlusion events indicate uneven device reliability, even though certain problems like User Interface, Sensor, and Software Malfunctions stayed low. These patterns demonstrate the necessity of focused CAPA strategies aimed at enhancing alarm systems, tubing integrity, and pump performance.

5. INFUSION PUMP RECALL TRENDS (2022-2024)



	2022	2023	2024
Total	27	37	55
Class III	0	0	1
Class II	9	22	36
Class I	18	15	18

Fig 7: Annual Infusion Pump Recalls by FDA (2022-2023)

From 2022 to 2024, the number of recalls for infusion pumps went up a lot. There were 28 recalls in 2022, 37 in 2023, and 55 in 2024, including a rare Class III recall. The FRN model always had the most recalls, going from 7 in 2022 to 43 in 2024, which is very similar to how often it broke down. It was responsible for 15 Class I recalls in both 2023 and 2024, which shows that there are serious

safety issues. Models like LKK had repeated Class II recalls, which showed that there were still moderate-risk problems. On the other hand, MEA and MRZ had Class I and II recalls in 2024, which showed that there were new quality problems. LZH, LZG, OPP, and PHC, on the other hand, had no recalls, which is in line with their lower rate of malfunctions. These patterns show how important it is to focus on specific CAPA measures and regulations, especially for devices like FRN.

6. GAPS IN REGULATORY COMPLIANCE OBSERVED (2022–2024 INFUSION PUMP ANALYSIS)

	REGULATORY AREA	REGULATORY BASIS	OBSERVED GAP / NON-CONFORMANCE	SUPPORTING EVIDENCE (2022–2024)
1	Design Validation & Verification	• FDA 21 CFR 820.30(f–g) • ISO 13485:2016, Clause 7.3.6	Inadequate real-use condition testing for hardware and software.	Pump malfunctions rose from 34 (2022) to 90 (2024). Spikes in error codes and infusion rate errors suggest poor design validation.
2	Corrective & Preventive Action (CAPA)	• FDA 21 CFR 820.100 • ISO 13485:2016, Clauses 8.5.2 & 8.5.3	Ineffective CAPA implementation leading to recurrence of critical issues.	FRN model continues to dominate Class I recalls and malfunction reports in 2023–2024 despite prior recalls.
3	Human Factors & Usability Engineering	FDA Guidance (2022)	Usability engineering not adequately addressed; alarm and UI issues may lead to operator errors.	Persistent alarm malfunctions (~54 cases in 2024), and UI errors were reported, indicating possible usability testing gaps.

Table 3: Gaps in Regulatory Compliance (2023-2024)

RECOMMENDED CAPA (CORRECTIVE AND PREVENTIVE ACTIONS)

1. Issue Identified

The FRN model accounts for 79% of all causes from 2022–2024, with 15 Class I recalls in both 2023 and 2024. Major recurring issues include pump malfunction (↑ from 34 to 90), alarm failure (↑ to 54), and tubing failure (↑ to 30).

2. Root Cause Analysis (RCA)

- Hardware failure in the pump drive mechanism.
- Alarm system design flaws (poor sensitivity or false negatives).
- Weak tubing connections or material degradation.
- Software glitches leading to infusion rate inaccuracies and error codes.

3. Corrective Actions (CA)

Action	Description
Hardware Redesign	Upgrade FRN's pump and tubing assembly with durable, validated materials.
Alarm System Audit	Conduct usability and functional testing on alarm algorithms and sensors.
Software Fixes	Patch firmware to reduce infusion rate error codes and prevent software lockups.
Batch Recall Follow-Up	Conduct failure mode investigation for Class I recall batches to stop further distribution.

Table 4: Corrective Actions (CA) targeting Identified Malfunctions and Recall Events

4. Preventive Actions (PA)

Action	Description
Risk-based PMCF	Implement post-market clinical follow-up specifically for FRN performance.
Predictive Maintenance	Integrate IoT or smart logging to detect pre-failure conditions.
Cross-functional Training	Conduct FRN-specific training for technicians and operators on proper usage and troubleshooting.
ISO 14971 Update	Reassess risk management file to cover newly identified hazards.

Table 5: Preventive Action Plan (PA) for Improving Infusion Pump Safety and Performance

CONCLUSION

This study offers a thorough analysis of the safety, malfunction trends, and regulatory supervision of infusion pumps from 2022 to 2024. The results show a consistent trend of device failures, mostly concentrated in one product category, including pump malfunctions, erroneous infusion rates, and alarm failures. Increased regulatory enforcement and manufacturer accountability are desperately needed, as evidenced by the dramatic rise in FDA recalls, particularly Class I events, and deficiencies in design validation, CAPA implementation, and usability engineering. Although infusion pumps are still essential for a variety of clinical settings, including critical care and neonatal medicine, it is impossible to overlook the dangers of subpar device performance and difficult user interfaces. Infusion therapy may become a safer, smarter, and more individualized modality in the future thanks to developments like digital twin technologies, AI-integrated DERS, and 3D-printed parts. Stakeholder cooperation, post-market surveillance, and strong quality assurance are necessary for these innovations to succeed in bridging compliance gaps and raising the bar for patient care.

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