Psurio

Post-market surveillance snapshot

Volumetric infusion pump (sample)

Controlled intravenous delivery of fluids and medicines to adults and children in hospital.

EU class IIb · FDA product code FRN

Surveillance period 15 October 2025 to 15 October 2026

Draft: 80 literature records still awaiting review

53 searches run and logged	**168** unique literature records	**0** records included
51,335 adverse-event reports	**24** FDA recalls	**15** signals to investigate

Prepared 15 October 2026 · Snapshot 2026-10-15-volumetric-infusion-pump-sample-858765

Prepared with Psurio

1. Signals worth investigating

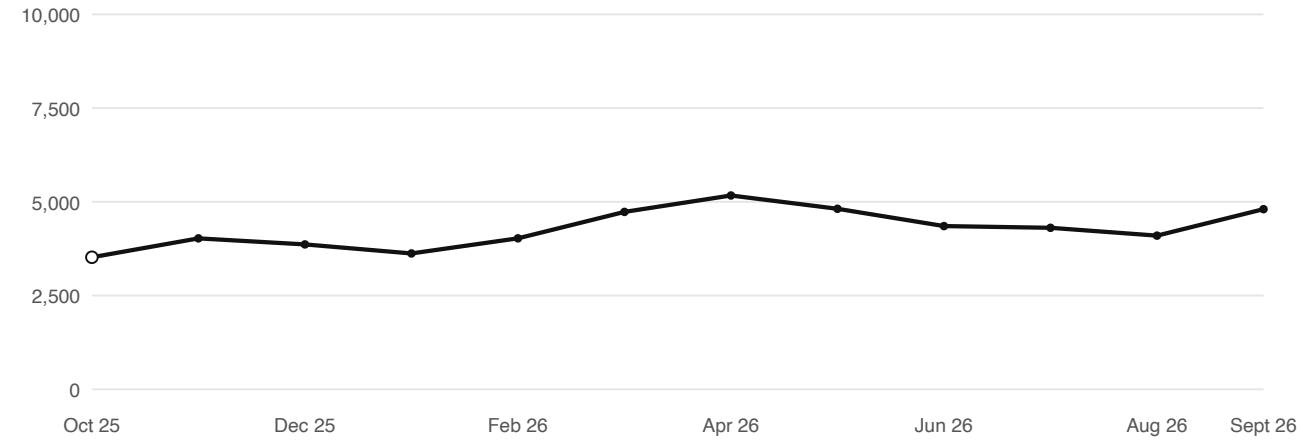
Priority	Signal	Evidence
high	Rising: Pumping Problem	179 reports in 2026-07-03 to 2026-09-30 (60.54/month), 15.27× the earlier monthly rate.
high	Rising: Moisture Damage	49 reports in 2026-07-03 to 2026-09-30 (16.57/month), 71.05× the earlier monthly rate.
high	Rising: Device Displays Incorrect Message	48 reports in 2026-07-03 to 2026-09-30 (16.23/month), 6.33× the earlier monthly rate.
high	Rising: Device Reprocessing Problem	44 reports in 2026-07-03 to 2026-09-30 (14.88/month), new in the recent window.
medium	Rising: Failure to Infuse	1109 reports in 2026-07-03 to 2026-09-30 (375.09/month), 2.03× the earlier monthly rate.
medium	ANSM field safety notice: Pompe à perfusion ambulatoire (accessoire) – Cassette-réservoirs CADD avec raccord NRFit – ICU Medical Inc.	2026-09-16: Rappel de produit · Rappel n° R2625748 destiné aux pharmacies d'usage intérieur et aux prestataires de santé à domicile (matched device term: pompe à perfusion).
medium	MHRA field safety notice: ICU Medical: CADD Medication Cassette Reservoirs with NRFit	2026-08-28: Infusion pump cassette (matched device term: infusion pump).
medium	BfArM field safety notice: Urgent Field Safety Notice for AlarisTM GW 800 Volumetric Pump by BD Switzerland Sarl	2026-08-05 (matched device term: volumetric pump).
medium	ANSM field safety notice: Pompe à perfusion Alaris GW 800 – BD	2026-08-04: Information aux utilisateurs · Information n° R2622916 destinée aux pharmacies d'usage intérieur, établissements de santé (matched device term: pompe à perfusion).
medium	Swissmedic field safety notice: MEDCAPTAIN LIFE SCIENCE CO., LTD.: BD neXus Disposable Infusion Set	2026-07-22: Electric infusion pump administration set, single-use (update) (matched device term: infusion pump).
medium	FDA recall by Baxter Healthcare Corporation (2 products)	Initiated 2026-08-11: A software issue that may occur during a Volume/Time (VOT) multi-syringe infusion when a syringe reaches empty and is replaced while a Volume To Be Infused (VTBI) remains.
medium	FDA recall by ICU Medical, Inc. (2 products)	Initiated 2026-06-10: In a specific scenario, the pump will not decrement the Volume to be Infused (VTBI) displayed on the Delivery screen and may deliver up to twice the VTBI at the programmed rate.
medium	FDA recall by ICU Medical, Inc.	Initiated 2026-05-12: Intravascular administration tubing set drip chambers may have black specks potentially due to the plastic molding process leaving discolored polyvinyl chloride

		(PVC) material within the drip chamber wall. The presence of discoloration and…
medium	FDA recall by Fresenius Kabi USA, LLC	Initiated 2026-05-06: Potential software anomaly that can cause the pump to report a false battery-health value (typically 69%) and trigger a battery-depletion alarm that will shut down the pump unless it is reconnected to AC mains power.
medium	FDA recall by Fresenius Kabi USA, LLC	Initiated 2026-05-06: Fresenius Kabi has been made aware via customer complaints that dropping or severe jarring of the Ivenix LVP may cause damage to internal components that may not be apparent or readily visible and the devices therefore remained in service.…
info	93 reports coded as death	MAUDE reports don't establish that the device caused the death. Read each narrative.
info	16 more field safety notices in the period	Listed in full in the field safety notices section.
info	13 more recall events in the period	Listed in full in the recalls table.

A signal is a prompt to investigate, not a conclusion. Thresholds: a monthly spike above the mean of earlier months plus two standard deviations; a problem reported at least twice as often per month in the last 90 days, with at least 5 reports; a complaint category significantly above its earlier rate (one-sided Poisson test, $p < 0.01$, at least 3 complaints).

2. Adverse events (FDA MAUDE)

Reports per month



Volumetric infusion pump (sample) (51,335 reports)

Hollow points are incomplete months. MAUDE data for this device runs to 2026-09-30. Counts are not adjusted for the number of devices in use.

Event types

Type	Reports
Malfunction	50,321
Injury	673

Other	248
Death	93

Device problems: last 90 days versus before

Recent: 2026-07-03 to 2026-09-30. Earlier: 2025-10-15 to 2026-07-02. Rates are per month. Rows marked “Exact count” were counted one problem at a time; rows marked “Estimate” come from the FDA’s list of the most frequent problems and may undercount less common ones.

Problem	Recent	Earlier	Recent / month	Earlier / month	Change	Count
Failure to Infuse	1,109	1,582	375.1	184.5	2.03×	Exact count
Pumping Problem	179	34	60.5	4	15.27×	Exact count
Moisture Damage	49	2	16.6	0.2	71.05×	Exact count
Device Displays Incorrect Message	48	22	16.2	2.6	6.33×	Exact count
Device Reprocessing Problem	44	0	14.9	0	new	Exact count
Material Discolored	44	0	14.9	0	new	Exact count
Leak/Splash	42	35	14.2	4.1	3.48×	Exact count
Inaccurate Flow Rate	34	41	11.5	4.8	2.4×	Exact count
Defective Device	24	31	8.1	3.6	2.25×	Exact count
Intermittent Infusion	23	14	7.8	1.6	4.76×	Exact count
Device Alarm System	2,129	3,649	720.1	425.6	1.69×	Estimate
Device Sensing Problem	1,787	5,882	604.4	686	0.88×	Estimate
Break	1,326	4,125	448.5	481.1	0.93×	Estimate
Failure to Sense	1,315	3,875	444.8	451.9	0.98×	Estimate
No Apparent Adverse Event	1,128	4,053	381.5	472.7	0.81×	Estimate

Most reported patient problems

Patient problem	Reports
No Clinical Signs, Symptoms or Conditions	48660
Insufficient Information	1110
Hyperglycemia	944
Low Blood Pressure/ Hypotension	153
Hypoglycemia	87
Appropriate Clinical Signs, Symptoms and Conditions Term/Code Not Available	85
High Blood Pressure/ Hypertension	50
Tachycardia	39
Hemorrhage/Blood Loss/Bleeding	36

Reaction to Medicinal Component of Device	32

FDA recalls in the period

24 recalled products in 18 recall events, newest first.

Initiated	Firm	Reason	Recall numbers	Status
2026-08-11	Baxter Healthcare Corporation	A software issue that may occur during a Volume/Time (VOT) multi-syringe infusion when a syringe reaches empty and is replaced while a Volume To Be Infused (VTBI) remains.	Z-3065-2026 Z-3066-2026	Open, Classified
2026-06-10	ICU Medical, Inc.	In a specific scenario, the pump will not decrement the Volume to be Infused (VTBI) displayed on the Delivery screen and may deliver up to twice the VTBI at the programmed rate.	Z-2723-2026 Z-2724-2026	Open, Classified
2026-05-12	ICU Medical, Inc.	Intravascular administration tubing set drip chambers may have black specks potentially due to the plastic molding process leaving discolored polyvinyl chloride (PVC) material within the drip chamber wall. The presence of discoloration and particulate matter in the fluid path has not been ruled out.	Z-3162-2026	Open, Classified
2026-05-06	Fresenius Kabi USA, LLC	Potential software anomaly that can cause the pump to report a false battery-health value (typically 69%) and trigger a battery-depletion alarm that will shut down the pump unless it is reconnected to AC mains power.	Z-2223-2026	Open, Classified
2026-05-06	Fresenius Kabi USA, LLC	Fresenius Kabi has been made aware via customer complaints that dropping or severe jarring of the Ivenix LVP may cause damage to internal components that may not be apparent or readily visible and the devices therefore remained in service. More specifically, drops or jarring on a hard surface can cause the touchscreen input cable to loosen, resulting in unintended touchscreen behavior on the LVP, including random screen touches and/or lack of screen responsiveness to user input. Under the reported failure condition, unintended touch inputs may register at arbitrary screen locations without user interaction. These inputs occur intermittently and without a predictable pattern.	Z-2224-2026	Open, Classified
2026-04-29	ICU Medical, Inc.	Under certain conditions, the pump may not display a soft limit alert, and will not notify the clinician of a soft limit violation before confirming and starting delivery. This may potentially lead to under- or over-delivery.	Z-2311-2026 Z-2312-2026 Z-2313-2026	Open, Classified
2026-02-11	CareFusion 303, Inc.	Due to product labeling not indicating which Transport Layer Security (TLS) version that must be enabled on hospital network to ensure secure Wi-Fi communication with Point-of-Care Units	Z-1645-2026	Open, Classified

2026-02-04	Fresenius Kabi USA, LLC	Potential for the Cassette Loading Lever to break.	Z-2274-2026	Open, Classified
2026-01-13	Baxter Healthcare Corporation	Pumps were released without full testing being performed, including occlusion alarm testing.	Z-1368-2026	Open, Classified
2025-12-15	ICU Medical, Inc.	ICU Medical received one lot of defective primary speakers from our supplier that may fail to produce an audible sound. If the primary speaker in your Plum Duo Infusion Pump fails, the pump may not produce audible alarms, alerts, or provide audible feedback for touchscreen inputs.	Z-1094-2026	Open, Classified
2025-12-15	ICU Medical, Inc.	Plum Solo and Duo Infusion pumps include a feature, that when selected, automatically flushes the downstream line after a piggyback therapy. The programmed flush volume is delivered from the primary line container at the piggyback therapy rate after the piggyback therapy is complete. In certain cases, as described below, the clinician may receive an Upper Hard Limit (UHL) or Lower Hard Limit (LHL) Violation message when programming a piggyback flush, which prevents the flush from being programmed.	Z-1118-2026 Z-1119-2026 Z-1120-2026	Open, Classified
2025-11-28	Baxter Healthcare Corporation	Certain pumps have potentially been released from service with defective grease applied to the cam and motor gears. Due to its low viscosity, the defective grease may lead to the device having insufficient lubrication on the cam, which could lead to premature wear of the mechanism assembly, resulting in over-infusion or a free-flow situation.	Z-1121-2026	Open, Classified
2025-11-21	Fresenius Kabi USA, LLC	Emphasizing instructions for LVP duration programming located in the IFU.	Z-1048-2026	Open, Classified
2025-11-14	Fresenius Kabi USA, LLC	Software version 5.10.1 and earlier contain anomalies that have the potential to cause serious patient harm or death.	Z-0885-2026	Open, Classified
2025-11-06	CareFusion 303, Inc.	Due to a number of modules flashed with a date and time associated with the daylight savings time (DST) adjustment that may cause connectivity issue with hospital networks. This issue only affects the Interoperability workflow for devices with a DST invalid timestamp, impacting connectivity of the PCU to the hospital network	Z-1217-2026	Open, Classified
2025-11-03	Fresenius Kabi USA, LLC	Incorrect assembly of specific lot of LVP Primary Administration Set that could result in serious patient injury.	Z-0586-2026	Open, Classified
2025-11-03	Fresenius Kabi USA, LLC	Downstream Occlusion alarms may occur during procedures using low flow infusion rates when a check valve* is added to the Ivenix Administration Set.	Z-0848-2026	Open, Classified
2025-10-17	CareFusion 303, Inc.	If infusion pump is dropped or severely jarred this may damage the pump module bezel assembly, which can cause under-infusion, over-infusion, unregulated flow, or	Z-0430-2026	Open, Classified

pump module failure to calibrate; so dropped/jarred pumps should be removed from use, tested, and inspected by qualified service personnel prior to reuse; tip sheet, cleaning and disinfecting procedure and reference guide updated.

3. Field safety notices (UK, Germany, France, Switzerland, Spain)

34 notices from European regulators (MHRA, BfArM, ANSM, Swissmedic, AEMPS) in the period, of which 13 only mention a search term inside the notice document.

Date	Source	Notice	Matched on
2026-09-16	ANSM Field safety notice	Pompe à perfusion ambulatoire (accessoire) – Cassette-réservoirs CADD avec raccord NRFit – ICU Medical Inc. Rappel de produit · Rappel n° R2625748 destiné aux pharmacies d'usage intérieur et aux prestataires de santé à domicile	device term: pompe à perfusion
2026-08-28	MHRA Field safety notice	ICU Medical: CADD Medication Cassette Reservoirs with NRFit Infusion pump cassette `Ref 40630462 2026/008/025/601/011`	device term: infusion pump
2026-08-05	BfArM Field safety notice	Urgent Field Safety Notice for AlarisTM GW 800 Volumetric Pump by BD Switzerland Sarl	device term: volumetric pump
2026-08-04	ANSM Field safety notice	Pompe à perfusion Alaris GW 800 – BD Information aux utilisateurs · Information n° R2622916 destinée aux pharmacies d'usage intérieur, établissements de santé	device term: pompe à perfusion
2026-07-22	Swissmedic Field safety notice	MEDCAPTAIN LIFE SCIENCE CO., LTD.: BD neXus Disposable Infusion Set Electric infusion pump administration set, single-use (update) `Ref Vk_20260713_032`	device term: infusion pump
2026-07-02	Swissmedic Field safety notice	B. Braun Melsungen AG: Infusomat Space P Bedside infusion pump, single-channel `Ref Vk_20260701_035`	device term: infusion pump
2026-03-31	MHRA Field safety notice	Abiomed, Inc: Impella Purge Cassette Infusion Pump Cassette · Model: 0043-0001;0043-0009 `Ref 39420703 2026/004/002/601/034`	device term: infusion pump
2026-02-16	ANSM Field safety notice	Pompe à perfusion ambulatoire (accessoires) – Set d'administration CADD à débit élevé – ICU Medical Inc. Rappel de produit · Rappel n° R2604556 destiné aux pharmacies d'usage intérieur des établissements de santé et aux prestataires de santé à domicile	device term: pompe à perfusion
2026-02-13	MHRA	ICU Medical: CADD High Volume Administration Sets	device term: infusion pump

	Field safety notice	Electric infusion pump administration set · Model: 21-7361-24 Ref 38755259 2026/002/010/601/028	
2026-02-12	Swissmedic Field safety notice	ICU Medical Inc: CADD™ High Volume Administration Sets Electric infusion pump administration set, single-use Ref Vk_20260210_023	device term: infusion pump
2026-02-05	ANSM Field safety notice	Pompe à perfusion (tubulure) – Sets de perfusion Alaris – BD Rappel de produit · Information n° R2602319 destinée aux pharmacies d'usage intérieur, établissements de santé	device term: pompe à perfusion
2026-01-28	MHRA Field safety notice	Baxter: EVO IQ Large Volume Pump Model: ELVP002UKI and 04400121200 Ref 38329736 2026/001/019/601/021	device term: large volume pump
2026-01-27	Swissmedic Field safety notice	BD Switzerland Sàrl: Alaris VP Infusion Sets Electric infusion pump administration set, single-use Ref Vk_20260122_01	device term: infusion pump
2026-01-21	MHRA Field safety notice	BD: Alaris VP Infusion Sets Infusion Pump Administration Set Ref 38309876 2026/001/014/601/056	device term: infusion pump
2025-12-17	ANSM Field safety notice	Pompe à perfusion BD neXus V700 et pousse-seringue – BD neXus S700 – Medcaptain Life Science Co. Information aux utilisateurs · Information n° R2534072 destinée aux pharmacies d'usage intérieur des établissements de santé	device term: pompe à perfusion
2025-12-16	BfArM Field safety notice	Urgent Field Safety Notice for BD Alaris System Infusion Pump by BD Switzerland Sarl	device term: infusion pump
2025-12-15	MHRA Field safety notice	MEDCAPTAIN MEDICAL TECHNOLOGY: BD neXus V700 Infusion Pump & S700 Syringe Pump V700: Infusion Pump; S700: Syringe Pump Ref 37923637 2025/012/008/601/002	device term: infusion pump
2025-12-01	MHRA Field safety notice	Baxter: Ambulatory Elastomeric Infusion Pumps Ref 37850863 2025/012/001/601/064	device term: infusion pump
2025-12-01	BfArM Field safety notice	Urgent Field Safety Notice for Ambulatory Elastomeric Infusion Pumps by Baxter Healthcare S. (Opfikon)	device term: infusion pump
2025-10-28	MHRA Field safety notice	Baxter Healthcare SA: EVO IQ Large Volume Pump 15th August 2025 Bedside infusion pump, single-channel MHRA reference: 37397515 2024/011/028/601/018 – Customer reply form · Model: ELVP001UKI Ref 37397515 2024/011/028/601/018	device term: infusion pump
2025-10-16	MHRA	ICU Medical: CADD-Solis Ambulatory Infusion Pumps	device term: infusion pump

	Field safety notice	Bedside infusion pump, single-channel · Model: CADD-Solis VIP Ref 37337852 2025/010/013/601/015

Mentioned only inside the notice document (BfArM)

BfArM's search matched these in the notice text. Check whether each concerns the device.

Date	Source	Notice	Matched on
2026-09-02	BfArM Field safety notice	Urgent Field Safety Notice for IntelliSpace Critical Care and Anesthesia by Philips Healthcare	device term: infusion pump (in document text)
2026-08-19	BfArM Field safety notice	Urgent Field Safety Notice for ORBIS Medication by DH Healthcare GmbH	device term: infusion pump (in document text)
2026-07-20	BfArM Field safety notice	Urgent Field Safety Notice for Infusomat Space P by B. Braun Melsungen AG , Sparte Hospital Care	device term: infusion pump (in document text)
2026-07-17	BfArM Field safety notice	Urgent Field Safety Notice for BD Alaris Plus and Alaris neXus Syringe Pumps by BD Switzerland Sarl	device term: infusion pump (in document text)
2026-07-16	BfArM Field safety notice	Urgent Field Safety Notice for Introducer Kit for Impella by Oscor, Inc	device term: smart pump (in document text)
2026-07-16	BfArM Field safety notice	Urgent Field Safety Notice for Introducer Kit for Impella by Oscor, Inc	device term: smart pump (in document text)
2026-07-15	BfArM Field safety notice	Urgent Field Safety Notice for Disposable Infusion Set by MEDCAPTAIN MEDICAL TECHNOLOGY CO ., LTD.	device term: infusion pump (in document text)
2026-05-07	BfArM Field safety notice	Urgent Field Safety Notice for Spaceplus Perfusor by B. Braun Melsungen AG	device term: infusion pump (in document text)
2026-04-20	BfArM Field safety notice	Urgent Field Safety Notice for Kaleido by ViCentra B.V.	device term: infusion pump (in document text)
2026-04-13	BfArM Field safety notice	Urgent Field Safety Notice for SynchroMed II Clinician Programmer Application by Medtronic Inc	device term: infusion pump (in document text)
2026-02-26	BfArM Field safety notice	Urgent Field Safety Notice for MyPTM App by Medtronic Inc	device term: infusion pump (in document text)
2026-01-23	BfArM Field safety notice	Urgent Field Safety Notice for AlarisTM VP Infusion Sets by BD Switzerland Sarl	device term: infusion pump (in document text)
2025-10-30	BfArM	Urgent Field Safety Notice for CamAPS FX App und CamAPS and mylife CamAPS by CamDiab Ltd	device term: smart pump (in document text)

	Field safety notice

4. Literature

Screening flow

Records found: 190

↓ 22 duplicates removed

Unique records: 168

↓ 88 excluded by rules

Decided by a person: 0 (0 excluded)

↓

Included: 0

80 still awaiting review

Decisions by relevance band

Records were ordered for review by a transparent relevance score (device in title or subject indexing, mentions in the abstract, safety topics). The score only ordered the work; every record was decided individually.

Band	Records	Included	Excluded	Awaiting
high	26	0	0	26
medium	15	0	0	15
low	127	0	88	39

Exclusions by reason

Code	Reason	Records
X3	No safety or performance data (editorial, news)	1
X1	Not the device type under surveillance	87

Included records and appraisal

No records included yet. Review the queue to complete this section.

5. Latest adverse-event reports

Received	Report
2026-09-30 Malfunction	**Spectrum IQ** BAXTER HEALTHCARE CORPORATION · 1314492-2026-02104 False Alarm

2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67346 Break; Contamination It was reported that the device was missing a piece. There was no patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67349 Circuit Failure; Physical Resistance/Sticking It was reported that the device had pump will not power on. There was no patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67350 Contamination It was reported that the device had not turning on, replaced battery, same issue. There was no patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67354 Device Sensing Problem It was reported that a failure was observed during a planned preventive maintenance or recall remediation service event. There was no reported patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67353 Calibration Problem It was reported that a failure was observed during a planned preventative maintenance, recall remediation, or repair order service event. "[Field Service]";"[Door ajar-safety clamp test failed]". There was no reported patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67347 Device Alarm System It was reported that the device had error code 242.4030. There was no patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67351 Circuit Failure It was reported that the device washed out screen. There was patient involvement but unknown harm.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67348 Failure to Sense It was reported that the device displayed channel error code 242.4030. There was no patient involvement.
2026-09-30 Malfunction	**Alaris System** CAREFUSION 303, INC. · 2016493-2026-67355 Premature Discharge of Battery It was reported that a failure was observed during a planned preventive maintenance or recall remediation service event. There was no reported patient involvement.
2026-09-30 Malfunction	**IVENIX INFUSION SYSTEM** FRESENIUS KABI USA, LLC · 3014732157-2026-04133 No Apparent Adverse Event The following has been reported:The unit was returned during service after initial complaint investigation was completed for rear housing issues. Secondary Findings: Unit experienced tubing set misloaded warnings due to sticky FVA pins. Pins and channels were cleaned and unit then passed a mock infusion.
2026-09-30 Malfunction	**IVENIX INFUSION SYSTEM** FRESENIUS KABI USA, LLC · 3014732157-2026-04134 No Apparent Adverse Event The following has been reported:The unit was returned during service after initial complaint investigation was completed for lever arm issues. Secondary Findings: Secondary Findings: Outlet FVA pin stuck in due to excess debris. FVA pin lip seals will be replaced during repair.

6. Limitations

- No manufacturer complaint data was imported. Trend reporting under MDR Article 88 relies on it.
- Embase was not searched (it is licensed). Notified Bodies often expect it for a full literature review.
- MAUDE covers reports made to the US FDA only, and anyone can submit one. Reports are not verified and don't prove the device caused the event.
- Report counts are not adjusted for how many devices are in use, so differences between devices may reflect sales volume.
- Recent months are incomplete because reports reach MAUDE weeks after the event.
- A sudden rise can come from one manufacturer filing many reports at once (for example after a recall or a complaint review), not only from new incidents. Check the narratives and manufacturers behind each rising problem.
- Field safety notices come from the MHRA (UK), BfArM (Germany), ANSM (France), Swissmedic (Switzerland), and AEMPS (Spain, which publishes selected safety notes rather than every notice). Not searched: the Italian Ministry of Health, whose site blocks automated requests; the TGA (Australia), which requires accepting its terms before its recall database can be queried; and Health Canada, which no longer publishes device recalls in its open data.
- Notices in French, Italian and Spanish are matched on brand and manufacturer names and on the device's terms in those languages; without them, notices that only describe the device type are missed.
- BfArM's search matches text inside notice documents, so some BfArM notices only mention the device in passing. These are marked and don't become signals on their own.
- Screening of literature was done by rules plus a person; the rules only exclude obviously out-of-scope records.
- openFDA MAUDE: Top 100 terms only; candidate signals are re-counted exactly.
- openFDA MAUDE: Top 100 terms only; candidate signals are re-counted exactly.
- MHRA: 54 weekly pages, 553 notices read.
- ANSM: 569 notices read, 5 matched.
- AEMPS: 34 notes in the period, 0 matched.

Appendix A. Searches run

Source	Query	Hits	Retrieved	Run at (UTC)
PubMed	`("infusion pump"[tiab] OR "volumetric pump"[tiab] OR "smart pump"[tiab] OR "large volume pump"[tiab] OR "Infusion Pumps"[mh]) AND ("adverse event"[tiab] OR "malfunction"[tiab] OR "device failure"[tiab] OR "equipment failure"[tiab] OR "recall"[tiab] OR "occlusion"[tiab] OR "alarm"[tiab] OR "free flow"[tiab] OR "over-infusion"[tiab] OR "under-infusion"[tiab] OR "medication error"[tiab] OR "programming error"[tiab] OR "dose error"[tiab] OR "drug library"[tiab] OR "use error"[tiab] OR "interoperability"[tiab] OR "Equipment Failure"[mh] OR "Equipment Safety"[mh] OR "Medication Errors"[mh] OR "Equipment Failure Analysis"[mh] OR "adverse effects"[sh]) | publication date 2025/10/15 to 2026/10/15`	167	167	2026-10-15 18:22:46
Europe PMC	`(TITLE_ABS:"infusion pump" OR TITLE_ABS:"volumetric pump" OR TITLE_ABS:"smart pump" OR TITLE_ABS:"large volume pump") AND (TITLE_ABS:"adverse event" OR TITLE_ABS:"malfunction" OR TITLE_ABS:"device failure" OR`	23	23	2026-10-15 18:22:46

	TITLE_ABS:"equipment failure" OR TITLE_ABS:"recall" OR TITLE_ABS:"occlusion" OR TITLE_ABS:"alarm" OR TITLE_ABS:"free flow" OR TITLE_ABS:"over-infusion" OR TITLE_ABS:"under-infusion" OR TITLE_ABS:"medication error" OR TITLE_ABS:"programming error" OR TITLE_ABS:"dose error" OR TITLE_ABS:"drug library" OR TITLE_ABS:"use error" OR TITLE_ABS:"interoperability") AND FIRST_PDATE:[2025-10-15 TO 2026-10-15] AND (SRC:MED OR SRC:PMC OR SRC:PPR)			
openFDA MAUDE	(device.device_report_product_code:"FRN") AND date_received:[20251015 TO 20261015] | count by date_received	51335	312	2026-10-15 18:22:47
openFDA MAUDE	(device.device_report_product_code:"FRN") AND date_received:[20260703 TO 20260930] | count by product_problems.exact	16623	100	2026-10-15 18:22:47
openFDA MAUDE	(device.device_report_product_code:"FRN") AND date_received:[20251015 TO 20260702] | count by product_problems.exact	49394	100	2026-10-15 18:22:47
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Failure to Infuse" AND date_received:[20260703 TO 20260930]	1109	1	2026-10-15 18:22:48
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Failure to Infuse" AND date_received:[20251015 TO 20260702]	1582	1	2026-10-15 18:22:48
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Pumping Problem" AND date_received:[20260703 TO 20260930]	179	1	2026-10-15 18:22:49
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Pumping Problem" AND date_received:[20251015 TO 20260702]	34	1	2026-10-15 18:22:49
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Moisture Damage" AND date_received:[20260703 TO 20260930]	49	1	2026-10-15 18:22:49
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Moisture Damage" AND date_received:[20251015 TO 20260702]	2	1	2026-10-15 18:22:49
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Device Displays Incorrect Message" AND date_received:[20260703 TO 20260930]	48	1	2026-10-15 18:22:50
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Device Displays Incorrect Message" AND date_received:[20251015 TO 20260702]	22	1	2026-10-15 18:22:50
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Device Reprocessing Problem" AND date_received:[20260703 TO 20260930]	44	1	2026-10-15 18:22:50
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Device Reprocessing Problem" AND date_received:[20251015 TO 20260702]	0	0	2026-10-15 18:22:51

openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Material Discolored" AND date_received:[20260703 TO 20260930]	44	1	2026-10-15 18:22:51
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Material Discolored" AND date_received:[20251015 TO 20260702]	0	0	2026-10-15 18:22:51
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Leak/Splash" AND date_received:[20260703 TO 20260930]	42	1	2026-10-15 18:22:52
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Leak/Splash" AND date_received:[20251015 TO 20260702]	35	1	2026-10-15 18:22:52
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Inaccurate Flow Rate" AND date_received:[20260703 TO 20260930]	34	1	2026-10-15 18:22:52
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Inaccurate Flow Rate" AND date_received:[20251015 TO 20260702]	41	1	2026-10-15 18:22:53
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Defective Device" AND date_received:[20260703 TO 20260930]	24	1	2026-10-15 18:22:53
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Defective Device" AND date_received:[20251015 TO 20260702]	31	1	2026-10-15 18:22:53
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Intermittent Infusion" AND date_received:[20260703 TO 20260930]	23	1	2026-10-15 18:22:53
openFDA MAUDE	(device.device_report_product_code:"FRN") AND product_problems.exact:"Intermittent Infusion" AND date_received:[20251015 TO 20260702]	14	1	2026-10-15 18:22:54
openFDA MAUDE	(device.device_report_product_code:"FRN") AND date_received:[20251015 TO 20261015] | count by event_type.exact	51335	4	2026-10-15 18:22:54
openFDA MAUDE	(device.device_report_product_code:"FRN") AND date_received:[20251015 TO 20261015] | count by patient.patient_problems.exact	51500	25	2026-10-15 18:22:54
openFDA MAUDE	(device.device_report_product_code:"FRN") AND date_received:[20251015 TO 20261015] | sorted by date_received:desc	51335	100	2026-10-15 18:22:55
openFDA recalls	(product_code:"FRN") AND event_date_initiated:[2025-10-15 TO 2026-10-15]	24	24	2026-10-15 18:22:57
MHRA	GOV.UK medical safety alerts of type field-safety-notices (and titled "Field Safety Notices"), published 2025-10-15 to 2026-10-15; each notice matched against: infusion pump, volumetric pump, smart pump, large volume pump, pompe à perfusion, pompes à perfusion,	553	9	2026-10-15 18:23:04

	Infusionspumpe, pompa infusionale, pompa per infusione, bomba de infusión			
MHRA	GOV.UK medical safety alerts of type device-safety-information, published 2025-10-15 to 2026-10-15; title and summary matched against the same terms	14	0	2026-10-15 18:23:04
BfArM	Field safety notices (Kundeninfo) containing "infusion pump", newest first, dated 2025-10-15 to 2026-10-15	14	14	2026-10-15 18:23:06
BfArM	Field safety notices (Kundeninfo) containing "volumetric pump", newest first, dated 2025-10-15 to 2026-10-15	3	3	2026-10-15 18:23:08
BfArM	Field safety notices (Kundeninfo) containing "smart pump", newest first, dated 2025-10-15 to 2026-10-15	4	4	2026-10-15 18:23:10
BfArM	Field safety notices (Kundeninfo) containing "large volume pump", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:13
BfArM	Field safety notices (Kundeninfo) containing "pompe à perfusion", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:14
BfArM	Field safety notices (Kundeninfo) containing "pompes à perfusion", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:16
BfArM	Field safety notices (Kundeninfo) containing "Infusionspumpe", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:17
BfArM	Field safety notices (Kundeninfo) containing "pompa infusionale", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:19
BfArM	Field safety notices (Kundeninfo) containing "pompa per infusione", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:20
BfArM	Field safety notices (Kundeninfo) containing "bomba de infusión", newest first, dated 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:21
ANSM	Informations de sécurité, dispositifs médicaux, 2025-10-15 to 2026-10-15; titles matched against 10 terms	569	569	2026-10-15 18:23:36
Swissmedic	FSCA publications matching "infusion pump", 2025-10-15 to 2026-10-15	15	15	2026-10-15 18:23:36
Swissmedic	FSCA publications matching "volumetric pump", 2025-10-15 to 2026-10-15	1	1	2026-10-15 18:23:36
Swissmedic	FSCA publications matching "smart pump", 2025-10-15 to 2026-10-15	2	2	2026-10-15 18:23:37

Swissmedic	FSCA publications matching "large volume pump", 2025-10-15 to 2026-10-15	1	1	2026-10-15 18:23:37
Swissmedic	FSCA publications matching "pompe à perfusion", 2025-10-15 to 2026-10-15	8	8	2026-10-15 18:23:37
Swissmedic	FSCA publications matching "pompes à perfusion", 2025-10-15 to 2026-10-15	4	4	2026-10-15 18:23:38
Swissmedic	FSCA publications matching "Infusionspumpe", 2025-10-15 to 2026-10-15	3	3	2026-10-15 18:23:38
Swissmedic	FSCA publications matching "pompa infusionale", 2025-10-15 to 2026-10-15	1	1	2026-10-15 18:23:39
Swissmedic	FSCA publications matching "pompa per infusione", 2025-10-15 to 2026-10-15	5	5	2026-10-15 18:23:39
Swissmedic	FSCA publications matching "bomba de infusión", 2025-10-15 to 2026-10-15	0	0	2026-10-15 18:23:39
AEMPS	Notas de seguridad de productos sanitarios, 2025-10-15 to 2026-10-15; titles and summaries matched against 10 terms	34	34	2026-10-15 18:23:40

Appendix B. Reason codes

Code	Meaning
I1	Safety outcome or adverse event
I2	Performance or clinical effectiveness
I3	Usability or use error
I4	State of the art or alternative therapies
X1	Not the device type under surveillance
X2	Non-human study
X3	No safety or performance data (editorial, news)
X4	Duplicate of another record
X5	Outside the surveillance period
R0	Needs a human decision