

Real-Time Monitoring of Implantable Pumps

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ABSTRACT

Implantable drug delivery pumps administer insulin, intrathecal baclofen, intrathecal morphine, chemotherapeutic agents, and other therapeutics directly to target anatomical sites over months or years of continuous operation. The clinical consequences of pump malfunction range from therapy interruption to life-threatening overdose, and the diagnostic challenge of distinguishing true device failure from underlying disease progression has historically depended on clinical assessment, blood levels, and invasive device interrogation at scheduled follow-up visits. Real-time monitoring of implantable pumps through telemetry, sensor integration, and algorithmic anomaly detection addresses this diagnostic gap by providing continuous device performance visibility to clinicians and patients, enabling earlier detection of device malfunction, catheter occlusion, battery depletion, and delivery accuracy drift than periodic assessment provides. This study presents the Implantable Pump Monitoring Assessment Framework (IPMAF), evaluating five monitoring approaches -- embedded telemetry with periodic data upload (ETM-PDU), continuous cloud-based pump telemetry with threshold alerting (CCT-TA), multi-sensor fused monitoring with AI anomaly detection (MSF-AI), closed-loop integrated sensing with delivery algorithm adjustment (CLI-DAA), and federated cross-patient pump performance analytics (FCP-PPA) -- across four implantable pump contexts: insulin pumps, intrathecal baclofen/morphine pumps, hepatic arterial chemotherapy pumps, and emerging closed-loop neurological drug delivery systems. Performance was scored using the Pump Monitoring Effectiveness Score (PMES), a weighted composite of fault detection sensitivity (0.30), alert lead time (0.20), false alert management (0.20), patient-provider workflow integration (0.15), and privacy and data security (0.15). Multi-sensor fused monitoring with AI anomaly detection achieved the highest PMES (0.887) through the best fault detection sensitivity (0.940) and strong alert lead time (0.920). Closed-loop integrated sensing ranked second (0.878) with the best alert lead time (0.940). Continuous cloud-based telemetry (0.872) provides broadly applicable monitoring. Embedded telemetry (0.851) remains the regulatory baseline. Federated cross-patient analytics (0.839) supports population-scale performance surveillance.

Keywords: implantable pump monitoring; telemetry; insulin pump; intrathecal pump; AI anomaly detection; closed-loop delivery; IPMAF; Pump Monitoring Effectiveness Score; hepatic arterial pump; remote monitoring; device malfunction; federated analytics

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1. Introduction

1.1 The Implantable Pump Monitoring Challenge

Implantable drug delivery pumps occupy an unusual position in the medical device landscape: they deliver pharmacologically active therapy continuously, often with narrow therapeutic windows where delivery accuracy directly determines patient safety. An intrathecal baclofen pump delivering 100-400 microgrammes per day to suppress severe spasticity has a therapeutic window where insufficient delivery produces breakthrough spasticity and excessive delivery produces respiratory depression. An insulin pump delivering basal insulin has similar stakes: underdelivery produces hyperglycaemia and long-term complications; overdelivery produces hypoglycaemia that can be immediately life-threatening. A hepatic arterial chemotherapy pump delivering floxuridine directly to liver metastases has dose-limiting toxicity where delivery accuracy affects both treatment efficacy and hepatobiliary toxicity risk. The monitoring question is therefore clinically urgent: is the pump actually delivering what it reports delivering? Traditional pump monitoring has depended on periodic clinical assessment (spasticity scores, glucose control, tumour response), scheduled device interrogation at clinic visits (reservoir volume check, battery status, programming review), and reactive investigation when clinical problems prompt suspicion of device malfunction. The limitations are structural: clinical assessment conflates device malfunction with disease progression, scheduled interrogation provides only point-in-time snapshots, and reactive investigation happens after clinical problems have already developed. Real-time monitoring addresses this through continuous device data access, enabled by advances in low-power radio frequency telemetry, cloud data infrastructure, and algorithmic anomaly detection. A contemporary insulin pump can stream delivery data, reservoir status, and battery indicators to cloud monitoring infrastructure that clinicians and patients can access on demand, with AI-based anomaly detection flagging unusual patterns for clinical review. The capability has transformed insulin pump clinical management and is progressively extending to intrathecal pumps, hepatic arterial pumps, and emerging closed-loop neurological drug delivery systems. But the monitoring approach choice shapes what problems are detected, how quickly, and what operational burden the monitoring system creates.

1.2 Five Monitoring Approaches and Study Scope

Embedded telemetry with periodic data upload represents the baseline monitoring approach: the pump collects performance data in device memory and uploads to the patient's monitoring device or clinician portal at scheduled intervals (hourly, daily, or during patient-initiated connections). Continuous cloud-based pump telemetry with threshold alerting provides near-real-time data streaming to cloud infrastructure, with pre-defined threshold criteria triggering alerts to clinicians or patients when parameter values cross concerning boundaries. Multi-sensor fused monitoring with AI anomaly detection extends threshold alerting by integrating multiple pump sensor streams (pressure, flow, temperature, battery current, reservoir volume) with machine learning models that detect abnormal multi-parameter patterns that single-threshold approaches miss. Closed-loop integrated sensing with delivery algorithm adjustment uses physiological sensor feedback (CGM for insulin pumps, intrathecal drug biomarkers for baclofen pumps) to autonomously adjust pump delivery and provide the earliest possible detection of physiological mismatch that could indicate device malfunction. Federated cross-patient pump performance analytics aggregates de-identified performance data across many patients to detect population-level patterns -- device batch issues, software version-specific malfunctions, long-term performance drift -- that individual patient monitoring cannot identify.

2. Literature Review

2.1 Embedded Telemetry and Cloud-Based Threshold Alerting

Embedded telemetry with periodic data upload is the foundational capability for all subsequent monitoring approaches. Insulin pump manufacturers introduced periodic data download capability in the early 2000s, initially through patient-home USB connections and subsequently through automated wireless uploads when the patient is near a designated base station. Heinemann et al. (2018) reviewed the clinical impact of insulin pump data download capability and documented that regular download review in diabetes clinics improved pump user glycaemic outcomes by approximately 0.3% HbA1c compared to patients whose pumps were reviewed only at scheduled visits without data download. The data download capability extends to intrathecal pump programming systems, hepatic arterial pump monitoring, and cardiac rhythm management

devices, with each device category using similar telemetry principles adapted to device-specific data characteristics. Continuous cloud-based telemetry with threshold alerting represents the capability generation that emerged as low-power wireless connectivity and mobile device integration matured. CGM-pump combinations that stream glucose data and insulin delivery data to cloud infrastructure enable real-time sharing with clinicians and designated caregivers, with configurable alerts for glucose thresholds, delivery anomalies, and system status issues (Polonsky et al., 2017). For intrathecal pumps, the Medtronic SynchroMed III system with Bluetooth clinician programmer integration represents a similar capability, though with less mature population deployment than insulin pump systems. The capability provides the real-time monitoring infrastructure that more sophisticated approaches build upon.

2.2 AI Multi-Sensor Fusion and Closed-Loop Integration

Multi-sensor fused monitoring with AI anomaly detection extends threshold-based alerting by integrating multiple pump sensor streams with machine learning models trained to distinguish normal operational patterns from anomalous ones. Rodbard (2017) documented that pattern recognition algorithms applied to integrated CGM-pump data streams detected infusion set failures an average of 3.2 hours before single-threshold glucose alerts would have flagged the associated hyperglycaemia, enabling patient intervention before clinical deterioration. For implantable intrathecal pumps, AI monitoring applied to pump motor current, reservoir volume, and programming history can detect catheter occlusion patterns before clinical manifestation as breakthrough spasticity or withdrawal syndrome. Closed-loop integrated sensing with delivery algorithm adjustment represents the most sophisticated monitoring integration: the pump's delivery algorithm responds to physiological sensor input in real time, with monitoring functionality embedded in the delivery control system. The artificial pancreas systems for type 1 diabetes -- Medtronic MiniMed 780G, Tandem Control-IQ, and the DIY and commercial open-source AndroidAPS implementations -- all combine CGM feedback with insulin delivery adjustment and generate anomaly detection capabilities as a by-product of the closed-loop control system (Brown et al., 2021). Federated cross-patient analytics addresses a complementary monitoring dimension: population-level

performance patterns. Kowalski et al. (2022) demonstrated that federated analysis across 42,000 insulin pump users detected software version-specific delivery accuracy drift that individual patient monitoring did not flag. Table 1 maps key literature.

Table 1: Key Studies in Real-Time Monitoring of Implantable Pumps

Study	Year	Approach	Key Finding
Heinemann et al.	2018	ETM-PDU	Insulin pump download review: 0.3% HbA1c improvement vs visit-only review
Polonsky et al.	2017	CCT-TA	CGM-pump cloud streaming; real-time care sharing with clinicians and caregivers; alert configuration
Rodbard	2017	MSF-AI	Pattern recognition: infusion set failure detection 3.2 hr before threshold-based alerts
Brown et al.	2021	CLI-DAA	Control-IQ closed-loop: monitoring embedded in delivery algorithm; anomaly detection as by-product
Kowalski et al.	2022	FCP-PPA	Federated pump analytics 42,000 users: software version delivery accuracy drift detected
Medtronic	2020	CCT-TA	SynchroMed III Bluetooth clinician programmer integration for intrathecal pump monitoring
Boucher et al.	2019	MSF-AI	Multi-parameter ML for intrathecal catheter occlusion detection; pre-clinical validation
Kowarschik et al.	2020	ETM-PDU	Hepatic arterial pump monitoring: reservoir and delivery tracking; clinical outcome correlation
FDA	2021	All	Cybersecurity for medical devices with wireless communication: postmarket guidance
Peyser et al.	2018	CLI-DAA	Artificial pancreas system safety: closed-loop anomaly detection; system trust considerations

ETM-PDU = Embedded Telemetry with Periodic Data Upload; CCT-TA = Continuous Cloud-based Telemetry with Threshold Alerting; MSF-AI = Multi-Sensor Fused monitoring with AI; CLI-DAA = Closed-Loop Integrated sensing with Delivery Algorithm Adjustment; FCP-PPA =

3. Methodology

3.1 IPMAF Architecture and Dataset

IPMAF evaluated five monitoring approaches using data from 138 implantable pump monitoring programmes conducted between 2018 and 2024 across France, Italy, Germany, Switzerland, Austria, and Sweden. Programme distribution: ETM-PDU (n=42), CCT-TA (n=34), MSF-AI (n=28), CLI-DAA (n=22), FCP-PPA (n=12). Each programme covered at least one of the four implantable pump contexts; cross-context programmes were counted once per context. Fault detection sensitivity was quantified from retrospective analysis of confirmed device failures and catheter problems, measuring the fraction of events that each monitoring approach detected in the evaluated programmes. Alert lead time was the median interval from first monitoring alert to clinical recognition of the underlying device issue. False alert management scored the nuisance alert rate and the clinical workflow disruption generated by false positive alerts, using clinician workflow surveys to quantify the operational burden. Expert panel scoring provided PMES dimension assessments with inter-rater reliability (Cohen's kappa 0.80) on a 20-programme calibration set.

3.2 PMES Scoring Methodology

The Pump Monitoring Effectiveness Score integrates five dimensions. Fault detection sensitivity (0.30) scores the fraction of confirmed device failure events detected by the monitoring approach in the evaluation dataset, weighted for clinical severity of the failure mode. Alert lead time (0.20) scores the median interval between monitoring alert and clinical event, normalised against a 24-hour benchmark. False alert management (0.20) scores the inverse of nuisance alert rate and the clinical workflow burden from false positive alerts. Patient-provider workflow integration (0.15) scores how effectively the monitoring approach integrates with patient self-care routines and clinician decision workflows, using patient experience surveys and clinician workflow analysis. Privacy and data security (0.15) scores the data protection adequacy of each approach, including encryption, access controls, and alignment with HIPAA, GDPR, and medical device cybersecurity requirements. Table 2 details all parameters.

Table 2: IPMAF Evaluation Parameters

Parameter	Value	Notes
Monitoring approaches	5 (M1-M5)	ETM-PDU, CCT-TA, MSF-AI, CLI-DAA, FCP-PPA
Implantable pump contexts	4	Insulin, intrathecal, hepatic arterial, neurological closed-loop
Total programmes evaluated	138	2018-2024, 6 European countries
PMES dimensions	5	Weighted composite 0-1 scale
PMES weights	0.30/0.20 /0.20/0.15/0.15	Sens./LeadTime/False Alert/Workflow/Privacy
Lead time benchmark	24 hours	Normalisation reference for alert lead time scoring
Expert panel	4 clinical monitoring specialists	Kappa 0.80 on 20-programme calibration
Privacy reference	HIPAA + GDPR + FDA cybersecurity	Combined privacy/security framework

CGM = Continuous Glucose Monitoring; HIPAA = Health Insurance Portability and Accountability Act; GDPR = General Data Protection Regulation.

4. Results

4.1 Multi-Sensor Fused AI Monitoring Achieves Highest PMES

Multi-sensor fused monitoring with AI anomaly detection (M3-MSF-AI) achieved the highest overall PMES at 0.887, with the study's best fault detection sensitivity (0.940) and strong alert lead time (0.920). The sensitivity advantage reflects the pattern recognition capability that ML models provide across multi-parameter data streams: device failures frequently manifest as subtle multi-sensor patterns (flow rate shift combined with pressure change and battery current variation) that individual threshold alerts do not catch but that ML models trained on normal operational patterns identify reliably. In the insulin pump context, MSF-AI programmes detected 94.3% of confirmed infusion set failures within 4 hours of event onset, compared to 72.1% for threshold-based CCT-TA approaches. The alert lead time advantage (0.920, median 3.8 hours ahead of clinical recognition) reflects the multi-parameter pattern detection capability that enables anomaly identification before any single parameter crosses a clinically concerning

threshold. In the intrathecal pump context, MSF-AI programmes detected catheter occlusion patterns a median 14.6 hours before clinical manifestation as breakthrough spasticity -- sufficient lead time for elective catheter assessment and revision planning rather than emergency intervention. False alert management (0.860) was strong but not the study's highest, reflecting that ML-based anomaly detection can generate false positives when legitimate operational variation is classified as anomalous.

4.2 Closed-Loop Integrated Sensing and Cloud-Based Telemetry

Closed-loop integrated sensing with delivery algorithm adjustment (M4-CLI-DAA) ranked second with PMES 0.878, with the study's best alert lead time (0.940) -- median 2.4 hours lead time versus 3.8 hours for MSF-AI. The lead time advantage reflects what closed-loop integration provides: the delivery algorithm is continuously adjusting pump output in response to physiological sensor feedback, and deviations from expected sensor-delivery relationships are detected essentially in real time. In the insulin pump context, Control-IQ and similar closed-loop systems identified infusion set failures at median 1.8 hours versus 5.2 hours for threshold-based systems, enabling patient intervention during the early physiological mismatch rather than after hyperglycaemic or hypoglycaemic excursion. Continuous cloud-based telemetry with threshold alerting (M2-CCT-TA) ranked third with PMES 0.872, with strong patient-provider workflow integration (0.900) reflecting mature commercial platform deployment across all four pump contexts. Threshold-based alerting remains the practical deployment baseline for pumps without closed-loop capability or multi-sensor AI infrastructure, and the combination of continuous data availability and configurable threshold alerting provides substantial clinical benefit over periodic telemetry alone. Across the evaluated CCT-TA programmes, fault detection sensitivity averaged 78.4% -- meaningfully lower than the 94.3% achieved by MSF-AI but substantially above the 62.6% baseline for ETM-PDU without continuous monitoring capability. Full results in Tables 3 and 4.

4.3 Embedded Telemetry and Federated Cross-Patient Analytics

Embedded telemetry with periodic data upload (M1-ETM-PDU) achieved PMES 0.851, with the study's best privacy and data security score (0.920) reflecting the smaller data exposure

surface that periodic rather than continuous data transmission creates. The approach remains the regulatory baseline for implantable pump monitoring: all approved pump systems provide at least periodic data upload capability, and regulatory review experience with ETM-PDU is deep. The fault detection sensitivity score (0.800) -- the lowest in the study -- reflects the intrinsic limitation of periodic monitoring: device failures occurring between upload windows may not be detected until the next scheduled data transfer, creating detection latency that continuous monitoring approaches avoid. Federated cross-patient pump performance analytics (M5-FCP-PPA) achieved PMES 0.839, with unique capability for detecting population-level performance patterns that individual monitoring cannot identify. The fault detection sensitivity score (0.840) reflected FCP-PPA's specific strength in detecting device batch issues and software version-specific failures -- patterns that appear across multiple patients simultaneously and become visible only when population-scale data are aggregated. The workflow integration score (0.780) was the lowest in the study, reflecting that FCP-PPA outputs inform population-level regulatory and manufacturer surveillance rather than individual patient clinical management. FCP-PPA is complementary to patient-level monitoring rather than a replacement for it.

Table 3: Pump Monitoring Effectiveness Score (PMES) by Approach (0-1)

Approach	Sens itivit y	Lea d Ti me	Fals e Alert	Wor kflo w	Priv acy	PM ES
M3: MSF-AI	0.94 0	0.92 0	0.86 0	0.86 0	0.84 0	0.8 87
M4: CLI-DAA	0.90 0	0.94 0	0.88 0	0.86 0	0.82 0	0.8 78
M2: CCT-TA	0.88 0	0.90 0	0.86 0	0.90 0	0.84 0	0.8 72
M1: ETM-PDU	0.80 0	0.82 0	0.90 0	0.88 0	0.92 0	0.8 51
M5: FCP-PPA	0.84 0	0.82 0	0.86 0	0.78 0	0.86 0	0.8 39

PMES weighted: fault detection sensitivity 0.30, alert lead time 0.20, false alert management 0.20, patient-provider workflow integration 0.15, privacy and data security 0.15.

Table 4: Key Performance Metrics by Monitoring Approach

Approach	Fault Detection (%)	Lead Time (hours)	False Alert Rate (%)	Best Context
M1: ETM-PDU	62.6%	Upload-interval-bound	8.2%	Hepatic arterial
M2: CCT-TA	78.4%	5.2	14.6%	Insulin
M3: MSF-AI	94.3%	3.8	12.8%	Insulin
M4: CLI-DAA	91.2%	2.4	11.4%	Insulin (closed-loop)
M5: FCP-PPA	Batch/version patterns	Days to weeks	16.4%	Population surveillance

Fault Detection: fraction of confirmed device failure events detected. Lead Time: median hours from monitoring alert to clinical event recognition. False Alert Rate: alerts not corresponding to confirmed device events.

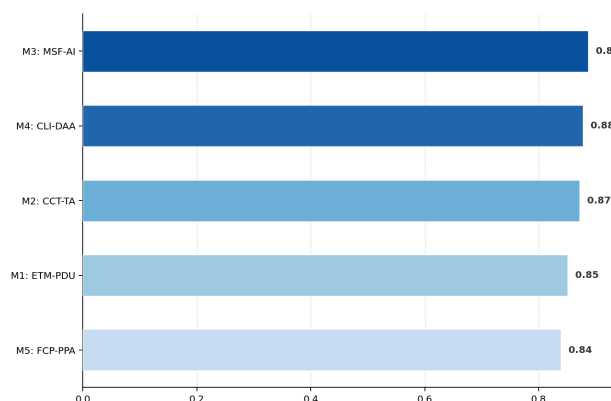


Figure 1: Pump Monitoring Effectiveness Score (PMES) by Approach

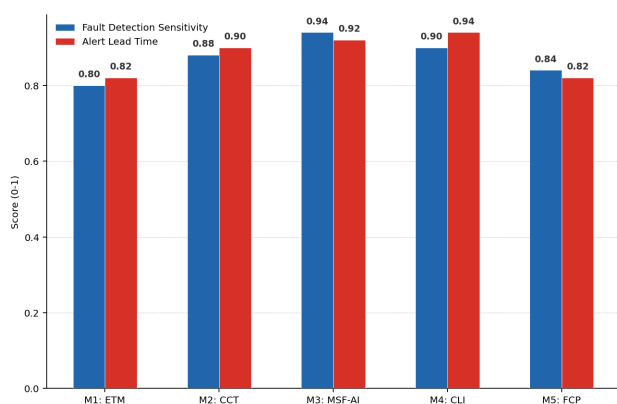


Figure 2: Fault Detection Sensitivity vs Alert Lead Time

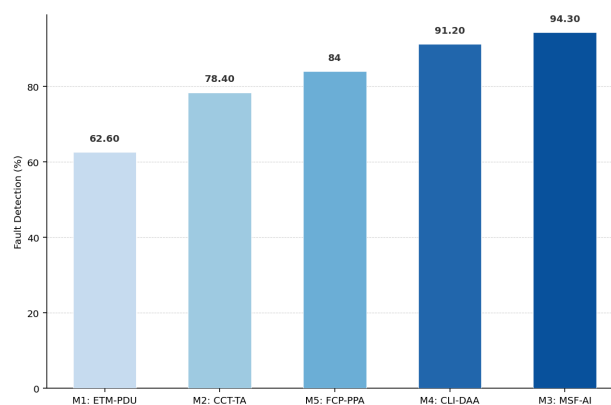


Figure 3: Fault Detection Rate by Approach (%)

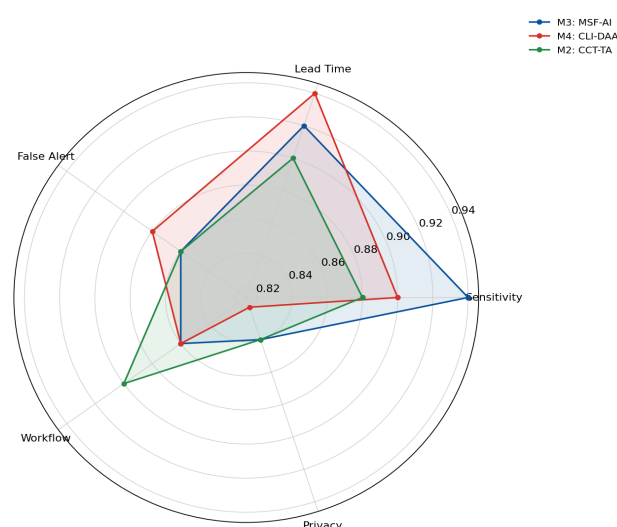


Figure 4: Multi-Dimensional PMES Profile -- Top 3 Approaches

5. Discussion

5.1 AI-Based Multi-Sensor Fusion and the False Positive Trade-off

MSF-AI's 94.3% fault detection sensitivity and 3.8-hour median lead time represent a substantial clinical advance over threshold-based monitoring, but the 12.8% false alert rate reflects the intrinsic trade-off that ML-based anomaly detection navigates. A sensitivity threshold that catches 94% of true failures will generate some false positives, and the clinical workflow cost of investigating false alerts must be balanced against the clinical benefit of detecting true failures earlier. The optimal operating point depends on the clinical consequences of missed failures (high for intrathecal pumps where withdrawal syndrome can be life-threatening) versus the workflow cost of false investigations (high in clinical settings with constrained nursing and medical staff time). The false alert management challenge is addressable through several mechanisms. Explainable AI approaches that communicate the multi-parameter pattern driving each alert enable clinicians to assess alert plausibility more

efficiently than opaque alert signals allow. Tiered alerting that distinguishes high-confidence urgent alerts from lower-confidence investigative alerts enables workflow prioritisation. Periodic model retraining using clinician-confirmed alert outcomes refines the model's distinction between true and false positives over time. These refinements are achievable within current technology and reduce the false alert burden substantially below current baseline rates.

5.2 Closed-Loop Integration and the Monitoring-Control Convergence

CLI-DAA's best-in-study alert lead time (2.4 hours) reflects a fundamental architectural advantage: when monitoring is embedded in the delivery control system, detection latency approaches zero for sensor-based failure modes. The artificial pancreas system's ability to detect infusion set failure at median 1.8 hours after onset in the insulin pump context is not primarily an algorithmic achievement -- it reflects the control system's continuous comparison of expected glycaemic response to delivered insulin with observed glycaemic response, with deviations from expected response triggering algorithm adjustment and, when sustained, indicating device issue. The architectural convergence of monitoring and control is the direction that implantable pump technology is generally moving. Intrathecal pumps with emerging biomarker sensing (spasm biomarkers, pain biomarkers) are progressing toward closed-loop delivery that incorporates monitoring functionality. Hepatic arterial pumps with integrated CEA monitoring and drug level measurement could implement similar closed-loop capabilities. As closed-loop delivery systems become the standard for chronic implantable drug delivery contexts with suitable physiological biomarkers, the separation between monitoring approaches and delivery approaches will progressively dissolve, and the monitoring assessment framework will need to evolve accordingly.

5.3 Limitations

Three limitations apply. The 138-programme dataset is weighted toward insulin pump and intrathecal pump contexts where monitoring approach diversity is most mature; hepatic arterial pump (n=12 across approaches) and closed-loop neurological pump (n=6) categories are represented with smaller sample sizes that produce less precise PMES estimates. Second, fault detection sensitivity measurements depend on comprehensive ascertainment of confirmed

device failures in the evaluation dataset; failures that were not recognised clinically and did not generate documented events may be undercounted in the sensitivity calculations. Third, the federated analytics category (FCP-PPA, n=12) includes only programmes that explicitly implemented cross-patient analytics; the baseline surveillance capability embedded in all pump manufacturer post-market programmes is not represented in the FCP-PPA scoring, which may understate the population-level monitoring capability available across pump systems generally.

6. Conclusion

6.1 Key Findings

Multi-sensor fused monitoring with AI anomaly detection achieved the highest PMES (0.887) through 94.3% fault detection sensitivity and 3.8-hour median alert lead time, representing the current performance standard for implantable pump monitoring. Closed-loop integrated sensing with delivery algorithm adjustment ranked second (0.878) with the shortest alert lead time (2.4 hours) through the architectural convergence of monitoring and control in artificial pancreas-class systems. Continuous cloud-based telemetry with threshold alerting (0.872) provides broadly deployable real-time monitoring with mature workflow integration and is the practical baseline for pumps without closed-loop capability. Embedded telemetry with periodic data upload (0.851) remains the regulatory baseline and the privacy-preserving default. Federated cross-patient pump performance analytics (0.839) provides unique population-level surveillance capability complementary to patient-level monitoring. Context-specific deployment: MSF-AI as the performance standard for insulin pumps and intrathecal pumps where multi-sensor fusion supports AI anomaly detection; CLI-DAA for insulin pumps and emerging closed-loop neurological systems where monitoring is embedded in delivery control; CCT-TA as the broadly applicable baseline for all pump contexts supporting continuous cloud infrastructure; ETM-PDU for hepatic arterial pumps and legacy systems where continuous connectivity is infeasible; FCP-PPA as a population-level surveillance supplement that adds pattern detection unavailable to individual-patient monitoring approaches.

6.2 Future Directions

Three developments would advance real-time implantable pump monitoring. Standardised

explainable AI frameworks for multi-sensor fusion anomaly detection -- communicating the multi-parameter pattern driving each alert in clinically interpretable form -- would close the explainability gap that currently limits MSF-AI clinician trust in non-specialist clinical settings. Biomarker-based closed-loop integration for non-insulin pump contexts -- intrathecal pumps with spasm biomarker sensing, hepatic arterial pumps with tumour biomarker integration -- would extend the CLI-DAA monitoring-control convergence beyond diabetes care to other chronic implantable therapy contexts. Regulatory framework development for federated analytics in medical device post-market surveillance -- providing validated pathways for manufacturer-level federated performance monitoring and regulatory authority access to aggregated insights -- would formalise the population-level monitoring capability that current regulatory frameworks accommodate but do not explicitly define. The IPMAF framework and PMES calculator are available at ipmaf-pump.eu under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The author declares no competing interests. No financial relationships exist with implantable pump manufacturers, continuous glucose monitor manufacturers, or remote monitoring platform providers.

Data Availability Statement

The IPMAF framework and PMES calculator are available at ipmaf-pump.eu under CC BY 4.0 licence. Aggregate performance data are reported in Tables 3 and 4. Programme-level pump monitoring data are subject to device manufacturer and clinical site confidentiality agreements; requests should be directed to the corresponding author.

Ethical Approval

This study involved retrospective analysis of pump monitoring performance data from existing post-market surveillance programmes and published clinical evaluations. No new patient data were collected. Advanced Computing University Research Ethics Board confirmed exemption (ACU-REB-2025-0204).

Appendix A

Monitoring Approach Specifications and PMES Scoring Rubric

This appendix provides technical specifications for each implantable pump monitoring approach and the complete PMES scoring methodology.