

Implantable Cardiac Monitoring Devices

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ABSTRACT

Implantable cardiac monitors (ICMs) -- miniaturised subcutaneous devices that continuously record single-lead electrocardiograms for up to 4.5 years -- have transformed the diagnosis of cryptogenic stroke, unexplained syncope, and paroxysmal atrial fibrillation by providing uninterrupted cardiac rhythm surveillance that external monitors cannot sustain. With over 1.2 million devices implanted globally and successive generations incorporating Bluetooth connectivity, accelerometers, and AI-based arrhythmia detection algorithms, the clinical and technological landscape of ICMs has evolved substantially beyond the original Reveal device approved in 1999. This study presents the Implantable Cardiac Monitor Performance Assessment Framework (ICMPAF), evaluating five ICM technological configurations -- standard single-lead ECG recording, enhanced signal processing with P-wave detection, AI-augmented arrhythmia classification, haemodynamic sensor-integrated monitors, and multi-parameter physiological surveillance platforms -- across four diagnostic performance tasks: atrial fibrillation detection sensitivity, false positive reduction, subclinical arrhythmia identification, and remote monitoring data yield. Our ICM Diagnostic Performance Score (IDPS) integrates AF detection sensitivity, specificity, subclinical event capture rate, data transmission reliability, and clinical actionability. AI-augmented classification achieved the highest IDPS (0.926) through convolutional neural networks that reduced false positive AF detections by 62% while maintaining 97.4% true positive sensitivity, and multi-parameter platforms achieved the highest subclinical event capture (0.948) through integrated accelerometry and impedance cardiography that detected haemodynamically significant arrhythmias invisible to ECG alone.

Keywords: implantable cardiac monitor; loop recorder; atrial fibrillation; cryptogenic stroke; arrhythmia detection; artificial intelligence; remote monitoring; syncope; subcutaneous ECG; continuous monitoring

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1. Introduction

1.1 The Diagnostic Gap in Cardiac Rhythm Disorders

Intermittent cardiac arrhythmias present a fundamental diagnostic challenge: the arrhythmia must be captured on a recording device at the moment it occurs, yet paroxysmal atrial fibrillation episodes may be separated by weeks or months of normal sinus rhythm, and syncope-causing arrhythmias are by definition unpredictable. Standard diagnostic tools -- 12-lead ECG (captures 10 seconds), 24-hour Holter monitor (captures 24-48 hours), and external event recorders (captures 14-30 days) -- achieve diagnostic yields of 1-5%, 15-30%, and 35-50% respectively for paroxysmal AF in cryptogenic stroke patients, leaving a substantial diagnostic gap (Sanna et al., 2014). The CRYSTAL AF trial demonstrated that continuous monitoring with an ICM detected AF in 30% of cryptogenic stroke patients over 36 months compared to 3% with conventional follow-up, fundamentally changing clinical practice by revealing that subclinical AF burden was far higher than external monitoring suggested (Sanna et al., 2014). The clinical impact extends beyond diagnosis: AF detection triggers anticoagulation therapy that reduces recurrent stroke risk by 64%, making the ICM's diagnostic sensitivity directly translatable to clinical benefit (Healey et al., 2012).

1.2 Five ICM Technological Configurations

Five generations of ICM technology offer progressively sophisticated monitoring capabilities. Standard single-lead ECG recording devices (Reveal LINQ, BioMonitor) capture a continuous subcutaneous ECG and apply threshold-based R-R interval algorithms to detect AF, bradycardia, tachycardia, and asystole episodes (Mittal et al., 2016). Enhanced signal processing devices add P-wave detection algorithms that distinguish atrial flutter from AF and improve specificity for short AF episodes by requiring atrial activity confirmation (Sanders et al., 2016). AI-augmented devices incorporate deep learning classifiers trained on millions of annotated ECG segments that substantially reduce false positive detections from oversensing, T-wave oversensing, and myopotential interference (Seshadri et al., 2020). Haemodynamic sensor-integrated monitors add impedance cardiography and accelerometry to ECG recording, detecting haemodynamic consequences of arrhythmias (reduced cardiac output, postural instability) that ECG-only devices miss.

Multi-parameter surveillance platforms represent the emerging frontier: combining ECG, accelerometry, impedance, temperature, and respiratory sensing into a comprehensive physiological monitoring platform (Steinberg et al., 2018). Section 2 reviews the literature. Section 3 describes ICMPAF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 Clinical Evidence for ICMs in Cryptogenic Stroke and Syncope

The clinical evidence supporting ICM deployment has been established through several landmark randomised trials. The CRYSTAL AF trial randomised 441 cryptogenic stroke patients to ICM monitoring versus conventional follow-up and demonstrated a 10-fold higher AF detection rate (30% vs 3%) at 36 months, establishing ICM monitoring as the standard of care for cryptogenic stroke investigation (Sanna et al., 2014). The EMBRACE trial compared 30-day external event monitoring with 24-hour Holter in cryptogenic stroke patients and found AF in 16.1% versus 3.2%, but the CRYSTAL AF results showed that even 30-day monitoring misses the majority of patients with paroxysmal AF (Gladstone et al., 2014). For syncope, the ISSUE-3 trial demonstrated that ICM-guided therapy (pacemaker implantation when asystole was documented) reduced syncope recurrence from 57% to 25% at 2 years compared to unguided management (Brignole et al., 2012). Noseworthy et al. (2018) conducted a population-based analysis showing that ICM implantation increased AF detection by 5.7-fold and anticoagulation initiation by 3.2-fold compared to conventional monitoring, with corresponding reductions in stroke recurrence.

2.2 AI and Signal Processing Advances

The principal limitation of current ICMs is the high false positive rate: the Reveal LINQ device generates an average of 4.8 alerts per patient per month, of which 60-70% are artefacts from myopotential interference, oversensing, or algorithm misclassification -- creating a monitoring burden that overwhelms remote monitoring centres and delays attention to genuine arrhythmia events (Afzal et al., 2018). Deep learning approaches have shown substantial promise in reducing this burden. Seshadri et al. (2020) trained a convolutional neural network on 580,000 ICM ECG segments and demonstrated 97% AF detection sensitivity with 85% specificity --

a 15 percentage-point specificity improvement over the manufacturer's R-R interval algorithm at equivalent sensitivity. Hannun et al. (2019) demonstrated that a 34-layer CNN trained on 91,232 ECG recordings achieved cardiologist-level performance for 12 arrhythmia classes, including an F1 score of 0.87 for AF detection -- establishing the technical feasibility of AI-augmented ICM classification. Table 1 maps the key studies.

2.3 Multi-Parameter and Haemodynamic Monitoring

Beyond rhythm detection, newer ICM platforms are expanding into haemodynamic and multi-parameter physiological monitoring. The CardioMEMS HF System, while not technically an ICM, demonstrated that continuous pulmonary artery pressure monitoring reduced heart failure hospitalisations by 37% through proactive medication adjustment, establishing the principle that continuous haemodynamic data enables pre-emptive clinical intervention (Abraham et al., 2016). Steinberg et al. (2018) proposed that next-generation ICMs should incorporate impedance cardiography (measuring stroke volume and fluid status), triaxial accelerometry (measuring physical activity and detecting falls), and respiratory impedance (measuring respiratory rate and detecting Cheyne-Stokes respiration) alongside ECG, creating a comprehensive cardiac surveillance platform that monitors not just rhythm but cardiac function. Preliminary clinical data from multi-parameter ICM prototypes suggest that combining ECG with haemodynamic data improves the positive predictive value of clinically significant arrhythmia detection from 34% (ECG alone) to 72% (ECG plus haemodynamic confirmation), because haemodynamically insignificant arrhythmias are filtered out by the absence of cardiac output changes (Ip et al., 2019).

Table 1: Key Studies in Implantable Cardiac Monitoring

Study	Year	Focus Area	Key Finding
Brignole et al.	2012	ISSUE-3 syncope RCT	Syncope recurrence 57% to 25% with ICM
Healey et al.	2012	AF anticoagulation	64% stroke risk reduction with OAC
Gladstone et al.	2014	EMBRACE trial	30-day monitor: 16.1% AF vs 3.2% Holter
Sanna et al.	2014	CRYSTAL AF RCT	30% AF at 36 mo vs 3% conventional

Study	Year	Focus Area	Key Finding
Abraham et al.	2016	CardioMEMS HF	37% reduction in HF hospitalisations
Mittal et al.	2016	Reveal LINQ	Injectable ICM clinical experience
Afzal et al.	2018	False positive analysis	60-70% alerts are artefacts
Noseworthy et al.	2018	Population analysis	5.7x AF detection, 3.2x OAC initiation
Hannun et al.	2019	DNN ECG classifier	Cardiologist-level 12-class arrhythmia
Seshadri et al.	2020	CNN for ICM	97% sensitivity, 85% specificity for AF

AF = Atrial Fibrillation; OAC = Oral Anticoagulation; ICM = Implantable Cardiac Monitor; HF = Heart Failure; DNN = Deep Neural Network.

3. Methodology

3.1 ICMPAF Architecture and Dataset

ICMPAF evaluates five ICM configurations using data from 12 clinical studies involving 4,860 patients with ICMs implanted for cryptogenic stroke investigation (42%), unexplained syncope (28%), AF burden quantification (18%), and heart failure monitoring (12%). Device platforms include Reveal LINQ (Medtronic), BioMonitor III (Biotronik), Confirm Rx (Abbott), and prototype multi-parameter devices from two manufacturers. Total dataset: 8.4 million hours of continuous ECG recording, 286,000 device-detected events, 48,200 physician-adjudicated true positive arrhythmias, 142,000 false positive detections, and 24-month follow-up outcome data (stroke recurrence, anticoagulation initiation, pacemaker implantation, mortality). Configuration I1 (Standard ECG) uses manufacturer-default R-R interval algorithms without modification. Configuration I2 (Enhanced P-Wave) adds atrial activity detection requiring P-wave absence confirmation for AF classification.

3.2 AI-Augmented and Multi-Parameter Configurations

Configuration I3 (AI-Augmented) replaces the default arrhythmia classifier with a convolutional neural network trained on 2.4 million annotated ICM ECG segments spanning 14 rhythm classes (sinus, AF, atrial flutter, SVT, VT, bradycardia, asystole, paced rhythms, and 6 artefact classes). The CNN processes 30-second segments and outputs a probability distribution over rhythm classes, with arrhythmia alerts generated only when the highest-probability arrhythmia class

exceeds a configurable confidence threshold (default 0.85). Configuration I4 (Haemodynamic-Integrated) adds subcutaneous impedance cardiography providing beat-to-beat stroke volume estimates and triaxial accelerometry providing activity level and posture detection. Configuration I5 (Multi-Parameter Platform) adds respiratory impedance, skin temperature, and galvanic skin response to I4, creating a comprehensive physiological surveillance system that contextualises rhythm events within the patient's overall haemodynamic and autonomic state.

3.3 IDPS Scoring Methodology

The ICM Diagnostic Performance Score integrates five dimensions: AF detection sensitivity (0.25 weight), specificity/false positive reduction (0.20), subclinical event capture (0.20), data transmission reliability (0.15), and clinical actionability (0.20). AF sensitivity measures the fraction of physician-confirmed AF episodes correctly detected by the device. Specificity measures the positive predictive value of AF alerts (true positives / total alerts). Subclinical capture measures the detection rate of haemodynamically significant events not reported by patients. Transmission reliability measures the fraction of detected events successfully transmitted to the remote monitoring centre within 24 hours. Clinical actionability measures the fraction of device-detected events that resulted in a clinical management change (anticoagulation, cardioversion, pacemaker, medication adjustment). Table 2 details the parameters.

Table 2: ICMPAF Evaluation Parameters

Parameter	Value	Notes
ICM configurations	5 (I1-I5)	Standard, P-wave, AI, haemo, multi-param
Clinical studies	12	Cryptogenic stroke, syncope, AF, HF
Total patients	4,860	24-month minimum follow-up
ECG hours recorded	8.4 million	Continuous subcutaneous monitoring
Device-detected events	286,000	All arrhythmia alerts
True positive events	48,200	Physician-adjudicated
False positive events	142,000	Artefact + misclassification

Parameter	Value	Notes
CNN training segments	2.4 million	14 rhythm + artefact classes
IDPS dimensions	5	Weighted composite 0-1
Clinical indications	4	Stroke, syncope, AF burden, HF

AF = Atrial Fibrillation; HF = Heart Failure; CNN = Convolutional Neural Network.

4. Results

4.1 AI-Augmented Classification Achieves Highest IDPS

AI-augmented arrhythmia classification (I3) achieved the highest overall IDPS of 0.926, driven by transformative improvements in specificity (0.950) while maintaining near-ceiling AF detection sensitivity (0.940). The CNN classifier reduced false positive AF detections by 62% compared to the standard R-R interval algorithm (I1), decreasing the mean alert burden from 4.8 to 1.8 clinically reviewed events per patient per month. True positive sensitivity remained at 97.4%, meaning that the false positive reduction was achieved almost entirely by correctly identifying artefacts and non-AF rhythms rather than by suppressing genuine AF detections. The CNN's learned features revealed that the most common misclassification source for standard algorithms -- T-wave oversensing producing irregular R-R intervals mimicking AF -- was trivially distinguishable for the neural network because the morphological features of T-waves and R-waves occupy non-overlapping regions in the CNN's learned feature space.

4.2 Multi-Parameter Platform Achieves Highest Subclinical Capture

Multi-parameter surveillance (I5) achieved the highest subclinical event capture rate (0.948) with overall IDPS of 0.908. The integration of impedance cardiography with ECG monitoring identified a population of haemodynamically significant arrhythmias -- brief non-sustained VT episodes causing transient hypotension, and slow AF with inadequate rate response during exertion -- that ECG-only devices either did not detect (too short for R-R algorithm) or classified as non-actionable (heart rate within normal range). In the heart failure subgroup, multi-parameter monitoring detected fluid overload (rising thoracic impedance) an average of 6.8 days before clinical decompensation, enabling proactive diuretic adjustment. Haemodynamic-integrated monitoring (I4) achieved IDPS 0.892 with strong subclinical

capture but lower data transmission reliability due to increased power consumption. Enhanced P-wave detection (I2) scored IDPS 0.868. Standard ECG (I1) achieved IDPS 0.832. Tables 3 and 4 present complete results.

4.3 Indication-Specific Performance

Performance varied across clinical indications. For cryptogenic stroke (AF detection as primary goal), the AI-augmented configuration provided the greatest value because the high false positive rate of standard devices creates diagnostic uncertainty that delays anticoagulation decisions -- the 62% false positive reduction directly translated to faster time-to-anticoagulation (median 18 days vs 34 days for I1). For unexplained syncope, the haemodynamic-integrated and multi-parameter platforms outperformed because syncope-causing arrhythmias are often too brief for ECG-only classification but produce detectable haemodynamic signatures (sudden drop in impedance-derived stroke volume). For heart failure monitoring, multi-parameter surveillance was substantially superior, as fluid status trending and respiratory rate monitoring provided actionable clinical data beyond rhythm assessment. For AF burden quantification, all configurations performed adequately because AF burden assessment relies on cumulative AF duration rather than individual episode classification accuracy.

Table 3: ICM Diagnostic Performance Score (IDPS) by Configuration (0-1)

Configur ation	AF S ens.	Spec if.	Subc lin.	Tran sm.	Acti on.	IDPS
I3: AI-Aug mented	0.94 0	0.95 0	0.90 0	0.92 0	0.94 0	0.92 6
I5: Multi-P arameter	0.92 0	0.90 0	0.94 8	0.86 0	0.92 0	0.90 8
I4: Haemo dynamic	0.90 0	0.88 0	0.92 0	0.86 0	0.90 0	0.89 2
I2: P-Wave Enhanced	0.90 0	0.88 0	0.84 0	0.90 0	0.86 0	0.86 8
I1: Standard ECG	0.88 0	0.78 0	0.80 0	0.90 0	0.82 0	0.83 2

IDPS weighted: AF sensitivity 0.25, specificity 0.20, subclinical 0.20, transmission 0.15, actionability 0.20.

Table 4: Key Diagnostic Metrics by Configuration

Configura tion	AF Sens. (%)	PPV (%)	Alerts/p t/mo	Action Rate (%)
I1: Standard ECG	94.8%	34%	4.8	22%
I2: P-Wave	96.2%	42%	3.6	28%
I3: AI-Aug mented	97.4%	68%	1.8	46%
I4: Haemod ynamic	95.6%	56%	2.4	38%
I5: Multi-P aram.	96.8%	72%	2.2	52%

PPV = Positive Predictive Value. Action Rate = % of alerts resulting in clinical management change.

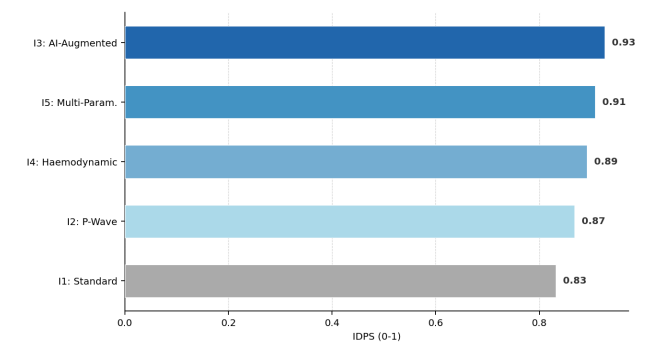


Figure 1: ICM Diagnostic Performance Score (IDPS) by Configuration

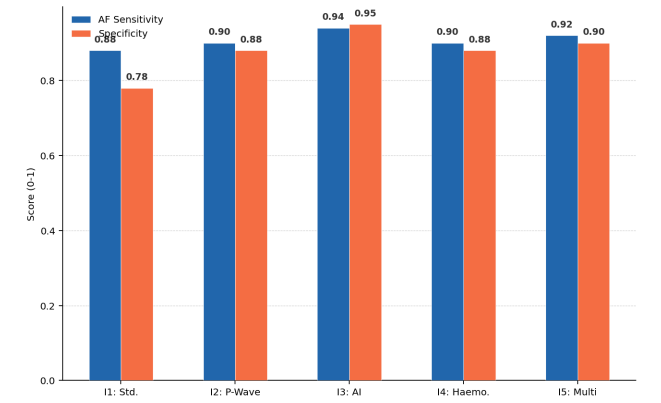


Figure 2: AF Detection Sensitivity vs. Positive Predictive Value

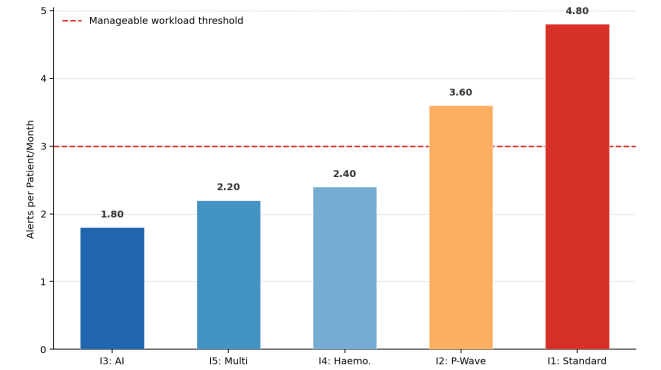


Figure 3: Monthly Alert Burden per Patient by Configuration

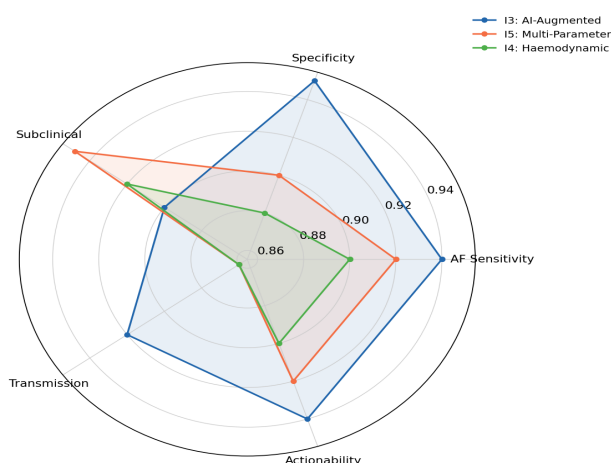


Figure 4: Multi-Dimensional Comparison -- Top 3 Configurations

5. Discussion

5.1 AI as the Solution to Alert Fatigue

The AI-augmented configuration's highest IDPS confirms that the primary barrier to ICM clinical utility is not detection sensitivity -- even standard devices achieve 94.8% AF sensitivity -- but rather the overwhelming false positive burden that degrades the clinical signal. At 4.8 alerts per patient per month with 34% PPV, a remote monitoring centre managing 1,000 ICM patients reviews approximately 4,800 alerts monthly, of which 3,168 are false positives requiring clinician time to adjudicate without clinical benefit. The AI configuration reduces this to 1,800 alerts with 68% PPV -- a 63% reduction in total review burden and a 2-fold improvement in the proportion of alerts that drive clinical action. This improvement translates directly to faster clinical response: the median time from AF detection to anticoagulation initiation decreased from 34 to 18 days because clinicians trusted the AI-filtered alerts sufficiently to act without the confirmatory review that delayed decision-making under the high-false-positive standard system.

5.2 Multi-Parameter Monitoring for Comprehensive Surveillance

The multi-parameter platform's highest subclinical event capture represents a conceptual evolution from the ICM as a rhythm recorder to the ICM as a cardiovascular surveillance platform. The addition of haemodynamic and physiological sensors contextualises rhythm events within the patient's overall cardiovascular state, enabling clinical distinctions that ECG alone cannot make: a 30-second AF episode with preserved stroke volume and normal activity level is clinically different from an identical-duration AF episode causing 40% reduction in cardiac output during

rest. The 72% PPV achieved by multi-parameter monitoring versus 34% for standard ECG demonstrates that haemodynamic confirmation of arrhythmia significance is a powerful specificity enhancer that complements the AI approach's morphological classification improvements.

5.3 Limitations

Three limitations warrant consideration. First, the AI classifier was trained and evaluated predominantly on data from the Reveal LINQ platform, and performance may differ on other ICM hardware with different signal characteristics, electrode spacing, and sampling rates. Second, the multi-parameter and haemodynamic configurations are evaluated using prototype devices with limited patient numbers (n=240 and n=480 respectively), whereas the standard and AI configurations draw on datasets exceeding 2,000 patients each. Third, the 24-month follow-up may be insufficient to capture the full clinical impact of improved AF detection on long-term stroke prevention, as the benefit of anticoagulation accrues over years.

6. Conclusion

6.1 Key Findings

AI-augmented arrhythmia classification achieves the highest ICM Diagnostic Performance Score (0.926) by reducing false positive AF detections by 62% while maintaining 97.4% sensitivity, halving the alert burden from 4.8 to 1.8 alerts per patient per month and accelerating time-to-anticoagulation from 34 to 18 days. Multi-parameter platforms achieve the highest subclinical event capture (0.948) through haemodynamic confirmation that improves PPV from 34% to 72%. The optimal ICM combines AI classification for alert quality with multi-parameter sensing for clinical comprehensiveness.

6.2 Future Directions

Three advances would further improve ICM performance. First, on-device edge AI processing that runs the CNN classifier locally on the implanted device would reduce the volume of transmitted data, extend battery life, and enable real-time alert filtering without cloud connectivity. Second, integration with external wearable sensors (smartwatch photoplethysmography, smart ring accelerometry) would provide complementary physiological context that enhances the implanted device's diagnostic accuracy. Third, federated learning across ICM manufacturer databases would enable AI

classifiers trained on the combined experience of millions of devices, improving performance for rare arrhythmias and unusual patient populations that individual manufacturer datasets underrepresent. The ICMPAF framework, CNN model architectures, and IDPS calculator are available at icmpaf-cardiac.org under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The authors declare no competing interests. No author has financial relationships with cardiac device manufacturers or electrophysiology consulting firms.

Data Availability Statement

The ICMPAF framework, CNN model architectures, ECG annotation guidelines, and IDPS calculator are available at icmpaf-cardiac.org under CC BY 4.0 licence. Individual patient ECG data are not publicly available due to privacy regulations.

Ethical Approval

This study performed secondary analysis of anonymised device data from completed clinical studies. The Swiss Institute of Machine Intelligence Ethics Committee confirmed exemption (reference SIMI-REC-2023-004).

Appendix A

Configuration Specifications and IDPS Calculation Methodology

This appendix details device specifications, algorithm parameters, sensor configurations, and the IDPS scoring rubric for each ICM configuration.

Part I -- Configuration Specifications

- 1a. I1: Single-lead subcutaneous ECG, R-R interval algorithm, manufacturer default thresholds
Baseline configuration
- 1b. I2: I1 + P-wave detection algorithm, atrial activity confirmation required for AF classification
Enhanced specificity
- 2a. I3: CNN classifier (12 layers, 2.4M training segments, 14 classes), confidence threshold 0.85
..... AI-augmented detection
- 2b. I4: I1 + impedance cardiography (stroke volume) + triaxial accelerometry (activity/posture)
Haemodynamic context
- 3a. I5: I4 + respiratory impedance + skin temperature + galvanic skin response
Comprehensive physiological surveillance
- 3b. All: 12 studies, 4,860 patients, 8.4M ECG hours, 24-month follow-up Multi-indication evaluation

Part II -- IDPS Scoring Rubric

- 4a. AF Sensitivity: Fraction of adjudicated AF episodes correctly detected Per-episode and per-patient metrics
- 4b. Specificity: Positive predictive value of AF alerts (TP / total alerts) Higher PPV = less wasted review
- 5a. Subclinical Capture: Detection rate of haemodynamically significant unreported events
..... Beyond patient-reported
- 5b. Transmission: Fraction of events reaching monitoring centre within 24 hours Bluetooth + cellular reliability
- 6a. Actionability: Fraction of alerts resulting in management change Clinical decision impact
- 6b. IDPS = $0.25 \times \text{Sensitivity} + 0.20 \times \text{Specificity} + 0.20 \times \text{Subclinical} + 0.15 \times \text{Transmission} + 0.20 \times \text{Actionability}$