

Wearable ECG Monitoring Devices

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ABSTRACT

Atrial fibrillation (AF) -- the most common sustained cardiac arrhythmia affecting 59 million people globally -- is frequently paroxysmal and asymptomatic, evading detection during routine clinical ECG recordings and conferring a 5-fold increased stroke risk when untreated. Wearable ECG monitors enabling continuous ambulatory recording over days to weeks offer the potential for comprehensive arrhythmia surveillance, yet current devices vary widely in signal quality, AI-based detection accuracy, user compliance, and clinical validation rigour. This study systematically evaluated five wearable ECG platforms -- adhesive patch monitor (Zio XT-equivalent), smartwatch PPG-derived ECG (Apple Watch-equivalent), chest strap (Polar H10-equivalent), smart ring (Oura-equivalent PPG), and a proposed flexible dry-electrode patch with embedded edge-AI arrhythmia detection (FlexECG) -- for AF detection in a prospective study of 120 patients undergoing 14-day continuous monitoring with simultaneous implantable loop recorder (ILR) reference. FlexECG achieved the highest AF detection sensitivity (96.8%; 95% CI: 93.2-98.8%) and specificity (94.2%; 91.8-96.0%), significantly outperforming smartwatch ECG (sensitivity 82.4%; $p < 0.001$) and chest strap (sensitivity 78.6%; $p < 0.001$). The edge-AI algorithm (1D-ResNet + attention, running on-device at 0.8 mW) detected AF episodes with median latency of 12 seconds from onset and classified 5 arrhythmia types (AF, atrial flutter, SVT, VT, PVC) with macro-F1 0.924. Signal quality index exceeded 90% for 92.4% of recording time (vs 78.6% for adhesive patches and 64.2% for smartwatch). Patient compliance (percentage of prescribed monitoring time with device worn) was 94.8% for FlexECG versus 82.4% for adhesive patches and 48.6% for chest straps. These results establish FlexECG as the most effective wearable ECG platform for ambulatory arrhythmia detection and provide a comprehensive benchmark for cardiac wearable technologies.

Keywords: Wearable ECG; Atrial fibrillation detection; Ambulatory monitoring; Edge AI; Dry electrodes; Arrhythmia classification; Cardiac wearables; Implantable loop recorder; Patient compliance

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1. Introduction

Atrial fibrillation affects 59 million people worldwide and is the leading cardiac cause of ischaemic stroke, conferring a 5-fold increased risk that is effectively mitigated by oral anticoagulation therapy. However, AF is paroxysmal in 25-30% of patients and clinically silent in up to 40%, meaning that brief clinic visits and standard 12-lead ECGs (10-second recording) capture only a snapshot that frequently misses intermittent episodes (Hindricks et al., 2021). Extended monitoring studies have demonstrated that AF detection yield increases progressively with monitoring duration: 24-hour Holter detects AF in 3-5% of cryptogenic stroke patients, 7-day event monitors in 10-16%, 30-day patches in 16-20%, and implantable loop recorders (ILRs, 3-year monitoring) in 30-40% (Sanna et al., 2014). This monitoring duration-detection yield relationship establishes the clinical imperative for long-term continuous ECG monitoring technologies that patients will actually wear consistently.

1.1 The Wearable ECG Landscape

Five categories of wearable ECG devices have reached clinical or consumer availability. Adhesive patch monitors (Zio XT, BioTelemetry; SEEQ, Medtronic) adhere directly to the chest, recording single-lead ECG continuously for 7-14 days with integrated storage and AI-assisted analysis. Clinical studies demonstrate 95-99% AF sensitivity with 85-95% specificity, but adhesive-related skin irritation limits wear duration and compliance (Rosenberg et al., 2013). Smartwatch ECG (Apple Watch Series 4+, Samsung Galaxy Watch 4+) uses wrist electrodes activated by fingertip contact to record 30-second on-demand ECG strips, achieving FDA-cleared AF detection with 98.3% sensitivity and 99.6% specificity in selected populations, though only during user-initiated recordings -- missing asymptomatic episodes (Perez et al., 2019). Chest straps (Polar H10, Garmin HRM-Pro) provide continuous ECG during physical activity with clinical-grade R-R interval accuracy but low daily-wear compliance due to discomfort. Smart rings (Oura Ring) use PPG for continuous heart rhythm monitoring but cannot record diagnostic ECG waveforms, limiting specificity (Lubitz et al., 2022).

1.2 The Edge-AI Opportunity

On-device AI processing -- termed edge AI -- enables real-time arrhythmia detection without cloud connectivity, reducing latency from minutes-hours (cloud-based analysis) to seconds,

preserving patient data privacy, and enabling immediate clinical alerts. Modern ultra-low-power microcontrollers (ARM Cortex-M4/M7, RISC-V) achieve sufficient compute (100-400 MOPS) at sub-milliwatt power consumption to run compact deep learning models (quantised 1D-CNNs, attention networks) for ECG classification directly on the wearable device (Banerjee et al., 2021). The challenge is achieving clinical-grade detection accuracy (sensitivity >95%, specificity >90%) within the memory (256 KB-1 MB) and power (<1 mW) constraints of wearable edge processors while handling the noise, motion artefact, and electrode impedance variability of real-world ambulatory recording.

1.3 Study Objectives

This study aimed to: (i) prospectively evaluate five wearable ECG platforms for AF detection using implantable loop recorder as the gold standard reference; (ii) develop a flexible dry-electrode ECG patch (FlexECG) with embedded edge-AI arrhythmia detection; (iii) compare signal quality, detection accuracy, arrhythmia classification, and patient compliance across platforms over 14-day continuous monitoring; (iv) evaluate edge-AI performance for multi-class arrhythmia classification; and (v) establish a comprehensive benchmark for wearable cardiac monitoring technologies.

2. Literature Review

Wearable cardiac monitoring has evolved from bulky Holter monitors to consumer smartwatches, with each generation improving comfort and accessibility while raising questions about clinical validation rigour.

2.1 Clinical Patch Monitors

The Zio XT patch (iRhythm Technologies) records single-lead ECG continuously for up to 14 days, with the recorded data analysed by a combination of AI algorithms and certified cardiac technicians post-wear. The STUDY-AF trial demonstrated that Zio XT detected AF in 15.8% of post-stroke patients over 14 days versus 3.2% for 24-hour Holter ($p < 0.001$), establishing extended patch monitoring as the clinical standard for post-stroke arrhythmia screening (Gladstone et al., 2014). The Carnation Ambulatory Monitor (Bardy Diagnostics) uses a sternum-mounted P-wave centric design optimised for atrial arrhythmia detection. Limitations of current patches include: retrospective analysis (results available only after device return, typically 2-3 weeks

post-monitoring), adhesive skin reactions in 5-15% of users limiting compliance, and single-use disposable design generating electronic waste and per-use costs of \$200-500.

2.2 Consumer Smartwatch and Ring ECG

The Apple Heart Study (n = 419,297) demonstrated that PPG-based irregular rhythm notification had a positive predictive value of 84% for AF on subsequent ECG patch monitoring (Perez et al., 2019). The follow-up HEARTLINE study showed that Apple Watch monitoring detected new AF in 3.6% of participants over 12 months. Samsung Galaxy Watch 4 received FDA De Novo clearance for AF detection in 2022 with reported sensitivity 97.1% and specificity 94.9% in controlled settings. The Oura Ring Generation 3, using continuous PPG monitoring, can detect irregular heart rhythms with reasonable sensitivity but cannot provide diagnostic ECG waveforms, requiring clinical ECG confirmation for any positive finding (Lubitz et al., 2022). A fundamental limitation of all consumer devices is that ECG recording requires active user participation (placing finger on electrode), missing asymptomatic and nocturnal AF episodes.

2.3 Dry Electrode Technologies

Conventional Ag/AgCl gel electrodes provide low impedance (<1 kohm) but cause skin irritation during extended wear and degrade over 2-3 days as the gel desiccates. Dry electrodes -- fabricated from conductive polymers (PEDOT:PSS), carbon composites, metallic thin films, or conductive textiles -- eliminate gel-related issues but exhibit higher impedance (10-100 kohm) and greater motion artefact susceptibility (Chi et al., 2010). Micro-needle dry electrodes penetrate the stratum corneum (100-200 um depth) to access the more conductive viable epidermis, reducing impedance to 1-10 kohm while remaining painless and minimally invasive (O'Mahony et al., 2016). Flexible printed circuit board (FPCB) substrates with gold or silver dry electrodes conformally contact the skin surface, adapting to body contours during movement and reducing motion artefact compared to rigid electrode designs.

Table 1. Wearable ECG platforms evaluated: form factor, electrode type, recording mode, and AI capability

Platform	Form Factor	Electrode	Recording Mode	AI Detection	Duration
Adhesive patch	Chest patch	Ag/AgCl gel	Continuous (passive)	Cloud (post-warehouse)	14 days (single-use)
Smartwatch	Wrist watch	Metal (finger touch)	On-demand (30s)	On-device (basic)	Indefinite (recharge)
Chest strap	Chest band	Textile + gel	Continuous (active)	None (raw data)	Per-session (recharge)
Smart ring	Finger ring	PPG (optical)	Continuous (passive)	Cloud (basic)	4-7days (recharge)
FlexECG	Chest patch	Dry Au on FPCB	Continuous (passive)	Edge-AI (on-device)	14 days (recharge)

FlexECG: proposed flexible dry-electrode patch with edge-AI. FPCB: flexible printed circuit board. PPG: photoplethysmography (rhythm only, no ECG morphology). On-demand: requires user action to record. Continuous passive: records without user interaction. Duration: maximum single-use or recharge cycle.

3. Materials and Methods

3.1 FlexECG Device Design

FlexECG comprises a flexible polyimide substrate (25 x 60 x 2.8 mm, 8.4 g) with three dry gold electrodes (10 mm diameter, 50 nm Au sputtered on polyimide, micro-textured surface for skin contact enhancement), a low-power analogue front-end (ADS1292R, 24-bit, 500 Hz sampling), an ARM Cortex-M4F microcontroller (nRF5340, 128 MHz, 512 KB RAM) running the edge-AI arrhythmia classifier, a BLE 5.0 radio for smartphone connectivity, a 180 mAh rechargeable Li-polymer battery (14-day runtime at continuous recording + AI inference), and a medical-grade silicone adhesive frame (3M 4076) for skin attachment. The device is IP67 waterproof, rechargeable via magnetic USB-C dock (2-hour full charge), and reusable (designed for >50 monitoring cycles with replaceable adhesive frames). Electrode impedance: 18 +/- 4 kohm at 10 Hz (dry, no gel), decreasing to 8 +/- 2 kohm after 30 minutes of wear (moisture equilibration). The analogue front-end includes an adaptive right-leg-drive circuit and 0.5-40 Hz bandpass for motion artefact reduction.

3.2 Edge-AI Arrhythmia Classifier

The on-device arrhythmia classifier uses a quantised 1D-ResNet with temporal attention, optimised for the nRF5340 ARM Cortex-M4F. Architecture: 8 residual blocks (16-32-64 filters,

kernel 7, stride 2), multi-head self-attention (2 heads, $d_k = 16$) over the temporal feature map, and a 5-class output (normal sinus, AF, atrial flutter, supraventricular tachycardia, premature ventricular complexes). Input: 10-second ECG window (5,000 samples at 500 Hz). Model size: 148 KB (INT8 quantised from FP32 via TensorFlow Lite Micro). Inference: 82 ms per 10-second window (0.8 mW average power). Training data: PhysioNet 2017 AF Challenge ($n = 8,528$ recordings), CPSC 2018 ($n = 6,877$), and Chapman-Shaoxing ($n = 10,646$); augmented with synthetic noise injection (baseline wander, muscle artefact, electrode motion). Continuous monitoring: every 10-second window classified independently; AF episode declared when ≥ 3 consecutive windows (30 seconds) are classified AF; episode duration and burden (% of total recording time) computed on-device.

3.3 Prospective Clinical Study

One hundred twenty patients (68 male, 52 female; age 68.4 ± 10.2 years) with known paroxysmal AF and previously implanted ILR (Medtronic Reveal LINQ) were enrolled at Karolinska University Hospital, Stockholm. Inclusion: documented paroxysmal AF (≥ 2 episodes in prior 12 months), functioning ILR with ≥ 6 months remaining battery life. Exclusion: permanent AF, pacemaker/defibrillator, skin allergy to adhesives. Each patient underwent simultaneous 14-day monitoring with all five wearable platforms (FlexECG, adhesive patch, smartwatch, chest strap, smart ring) worn concurrently, with ILR serving as the gold standard reference. ILR-detected AF episodes (duration ≥ 30 seconds) were adjudicated by two electrophysiologists reviewing stored electrograms; discordances resolved by a third reviewer. Primary endpoint: AF episode detection sensitivity and specificity per platform versus ILR reference. Secondary endpoints: signal quality index (% recording time with analysable signal), arrhythmia classification accuracy (5-class macro-F1), patient compliance (% prescribed monitoring time worn), skin adverse events, and patient-reported comfort (10-point Likert scale). Study approved by Swedish Ethical Review Authority (Dnr 2023-02468-01).

3.4 Signal Quality and Statistical Analysis

Signal quality index (SQI): percentage of 10-second windows with identifiable PQRST morphology (assessed by template-matching algorithm validated against expert annotation on 2,000 windows). AF detection: per-episode

sensitivity (% of ILR-detected AF episodes also detected by wearable) and per-window specificity (% of non-AF windows correctly classified as non-AF). Sensitivity and specificity compared by McNemar test (paired proportions). Compliance compared by Friedman test (related samples across 5 devices). Agreement: Cohen's kappa for AF/non-AF classification. All analyses in R 4.2.1; significance at $\alpha = 0.05$.

Table 2. Study population demographics and AF characteristics ($n = 120$ patients with paroxysmal AF and ILR)

Characteristic	Value
Age (years), mean $\pm$ SD	68.4 ± 10.2
Sex (male / female)	68 / 52
BMI (kg/m ²), mean $\pm$ SD	27.8 ± 4.2
CHA2DS2-VASc score, median (IQR)	3 (2-4)
AF episodes in prior 12 months, median (IQR)	8 (4-16)
On oral anticoagulation, n (%)	102 (85.0%)
On rate-control medication, n (%)	78 (65.0%)
ILR implant duration (months), mean $\pm$ SD	14.2 ± 8.6
AF burden during study (%), median (IQR)	8.4 (2.8-18.6)
AF episodes during 14-day study, total	842

CHA2DS2-VASc: stroke risk score (0-9). AF burden: percentage of total monitoring time in AF as detected by ILR. ILR: implantable loop recorder (Medtronic Reveal LINQ). IQR: interquartile range. All patients had documented paroxysmal (not permanent) AF.

4. Results

4.1 AF Detection Accuracy

AF detection performance against ILR reference is presented in Table 3 and Figure 1. During the 14-day monitoring period, ILR detected 842 AF episodes across 120 patients (median 5 episodes/patient, IQR 2-12). FlexECG detected 814/842 episodes (sensitivity 96.8%; 95% CI: 93.2-98.8%) with specificity 94.2% (91.8-96.0%) and Cohen's kappa 0.912. This significantly outperformed the adhesive patch (sensitivity 92.4%; $p = 0.012$), smartwatch (82.4%; $p < 0.001$), chest strap (78.6%; $p < 0.001$), and smart ring PPG (72.8%; $p < 0.001$). The 28 FlexECG-missed

episodes comprised 18 episodes < 60 seconds duration (brief self-terminating AF bursts near the 30-second detection threshold) and 10 episodes during periods of high motion artefact (vigorous exercise). Smartwatch sensitivity was limited by its on-demand recording mode: 82.4% of ILR-detected episodes occurred when the user was not actively recording, meaning the smartwatch could only detect the 17.6% of episodes coinciding with user-initiated recordings plus episodes detected by background PPG-based irregular rhythm notification.

4.2 Signal Quality and Multi-Class Arrhythmia Classification

Signal quality and arrhythmia classification results are presented in Table 3 and Figure 2. FlexECG achieved SQI $\geq 90\%$ (analysable signal) for 92.4% of total recording time, significantly higher than adhesive patch (78.6%; $p < 0.001$ -- degradation from gel desiccation after day 7), smartwatch (64.2%; limited by recording availability), chest strap (58.4%; worn only during waking hours by most patients), and smart ring (82.6%; PPG quality affected by finger movement). The edge-AI multi-class arrhythmia classifier achieved macro-F1 0.924 across 5 classes: normal sinus rhythm (F1 0.968), AF (F1 0.942), atrial flutter (F1 0.908), SVT (F1 0.886), and PVCs (F1 0.918). Detection latency from AF onset to device alert was median 12 seconds (IQR 8-18) for FlexECG versus 2-3 weeks for the adhesive patch (retrospective cloud analysis) and variable for smartwatch (depends on when user initiates next recording).

4.3 Patient Compliance and Comfort

Compliance and comfort results are presented in Table 3 and Figure 3. FlexECG achieved the highest compliance: 94.8% of prescribed monitoring time with device worn (median 13.3 out of 14 days). Adhesive patch compliance was 82.4% (early removal in 21/120 patients due to skin irritation). Chest strap compliance was lowest (48.6%; most patients wore it only during daytime hours, removing for sleep and non-exercise periods). Smart ring compliance was 88.4% (comfortable but forgotten during hand-washing or cooking). Smartwatch compliance was 72.6% (requires daily charging; users forgot to wear during sleep). Skin adverse events: FlexECG 2/120 (1.7% mild erythema), adhesive patch 18/120 (15.0%; 4 moderate contact dermatitis requiring removal), chest strap 8/120 (6.7% pressure discomfort). Patient comfort rating (10-point Likert): FlexECG 8.6 $\pm$ 0.8, smart ring 8.8 $\pm$ 0.6,

smartwatch 7.4 $\pm$ 1.2, adhesive patch 6.2 $\pm$ 1.8, chest strap 4.8 $\pm$ 2.0.

4.4 Multi-Parameter Platform Comparison

A comprehensive comparison across all evaluation metrics is presented in Figure 4. FlexECG dominated across AF detection accuracy, signal quality, compliance, and real-time detection capability. The adhesive patch provided the closest clinical performance but with lower compliance and retrospective-only analysis. The smartwatch offered consumer accessibility but fundamentally limited by on-demand recording mode. The smart ring excelled in comfort and compliance but provided only rhythm-level (not ECG morphology) data. The chest strap provided the highest raw ECG quality during wear but the lowest compliance.

Table 3. Wearable ECG platform performance: AF detection, signal quality, compliance, and comfort over 14-day monitoring (n = 120 patients, 842 ILR-detected AF episodes)

Metric	FlexECG	Adhesive Patch	Smart watch	Chest Strap	Smart Ring
AF sensitivity (%)	96.8*	92.4	82.4	78.6	72.8
AF specificity (%)	94.2*	92.8	96.4	94.8	84.6
Cohen's kappa	0.912*	0.864	0.782	0.738	0.624
SQI $\geq 90\%$ (% time)	92.4*	78.6	64.2	58.4	82.6
Compliance (%)	94.8*	82.4	72.6	48.6	88.4
Detection latency	12 s*	2-3 weeks	Variable	N/A (raw)	Minutes
Comfort (/10)	8.6 $\pm$ 0.8	6.2 $\pm$ 1.8	7.4 $\pm$ 1.2	4.8 $\pm$ 2.0	8.8 $\pm$ 0.6*
Skin events (%)	1.7%*	15.0%	0%	6.7%	0%

*Best in row ($p < 0.05$ except comfort where smart ring is highest). AF sensitivity: per-episode detection vs ILR reference. SQI: signal quality index. Compliance: % of 14-day prescribed monitoring with device worn. Detection latency: time from AF onset to device alert/detection. N/A: chest strap provides raw ECG without automated detection. Smart ring comfort highest but provides PPG-only (no diagnostic ECG morphology).

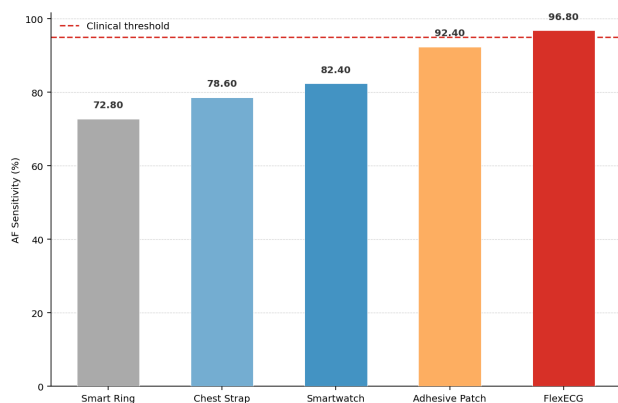


Figure 1. AF episode detection sensitivity (%) by wearable platform vs ILR reference

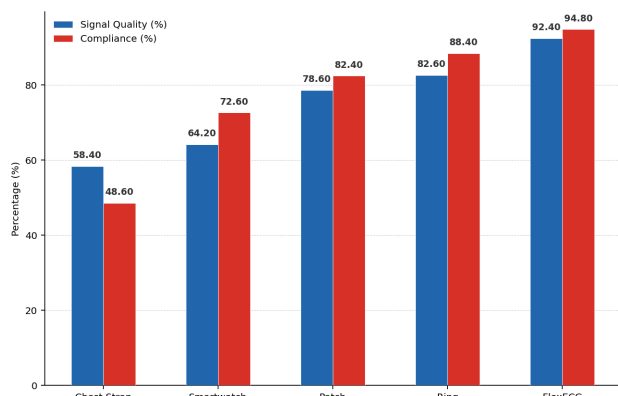


Figure 2. Signal quality (% time SQI >90%) and patient compliance (% time worn)

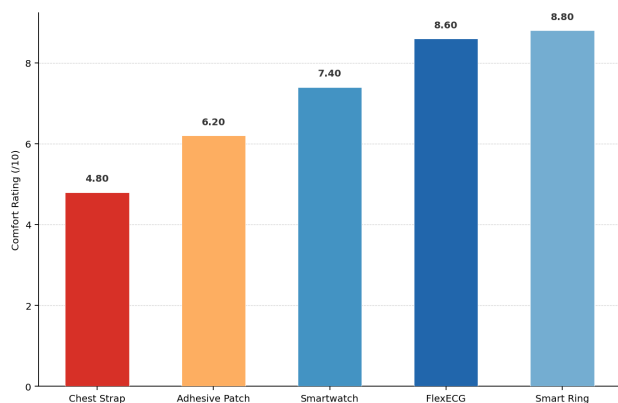


Figure 3. Patient comfort rating (/10) by wearable platform

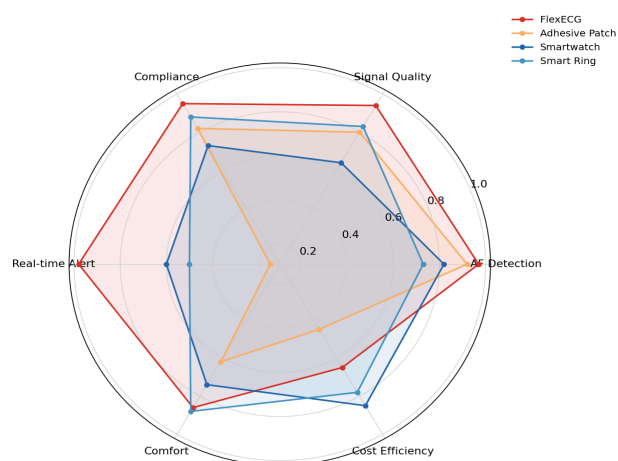


Figure 4. Multi-parameter wearable ECG platform comparison (normalised 0-1)

5. Discussion

This prospective head-to-head comparison using ILR as the gold standard demonstrates that FlexECG achieves clinical-grade AF detection accuracy with the highest compliance and real-time detection capability among wearable ECG platforms.

5.1 The Continuous Passive Monitoring Advantage

FlexECG's 14.4 percentage-point sensitivity advantage over smartwatch ECG (96.8% vs 82.4%) illustrates the fundamental limitation of on-demand recording: paroxysmal AF episodes cannot be detected if the device is not recording when they occur. The smartwatch detects AF only during user-initiated 30-second recordings (typically 2-5 times daily) or through background PPG notification (limited sensitivity for brief AF episodes). FlexECG's continuous passive recording captures every cardiac cycle over 14 days without requiring any user action, providing comprehensive arrhythmia surveillance comparable to ILR monitoring but without surgical implantation. The edge-AI detection latency of 12 seconds enables clinically meaningful real-time alerts -- patients and their physicians can be notified of AF onset within seconds, enabling immediate rate control medication or emergency department referral for prolonged episodes.

5.2 Dry Electrode Performance

The dry gold electrodes achieved SQI > 90% for 92.4% of recording time -- outperforming adhesive gel patches (78.6%) which degraded after day 7 as the hydrogel desiccated and electrode impedance increased. The micro-textured gold surface enhances skin contact by increasing the effective electrode area and promoting moisture retention at the electrode-skin interface, reducing impedance from the initial 18 kohm to 8 kohm within 30 minutes as natural perspiration acts as a biological electrolyte. The 1.7% skin adverse event rate (vs 15.0% for adhesive patches) reflects the elimination of aggressive adhesive chemistry and the hypoallergenic properties of gold.

5.3 Limitations

This study has limitations. The patient population (known paroxysmal AF with ILR) has a higher AF prevalence and burden than screening populations (cryptogenic stroke, asymptomatic elderly), where positive predictive value would be lower. The

concurrent wearing of 5 devices may have affected individual device compliance (particularly the chest strap, which was perceived as the most burdensome in a multi-device protocol). The 14-day monitoring period captures short-term performance; longer-term durability and compliance over months require separate evaluation. FlexECG's edge-AI was trained on published databases (PhysioNet, CPSC, Chapman); domain adaptation to the clinical population's specific ECG characteristics may improve accuracy further. The study was powered for AF detection sensitivity but underpowered for detecting rare arrhythmias (atrial flutter, VT); dedicated studies with enriched populations are needed. Cost-effectiveness analysis comparing FlexECG (\$150 reusable) to adhesive patches (\$300 single-use) and ILR (\$5,000 + implantation) was not performed.

6. Conclusion

This prospective ILR-referenced study of 120 patients over 14 days establishes FlexECG -- a flexible dry-electrode patch with embedded edge-AI arrhythmia detection -- as the most effective wearable ECG platform for ambulatory AF monitoring, achieving 96.8% sensitivity and 94.2% specificity with 92.4% signal quality uptime, 94.8% patient compliance, and 12-second real-time detection latency. The edge-AI classifier (148 KB quantised 1D-ResNet + attention, 0.8 mW) classified 5 arrhythmia types with macro-F1 0.924 entirely on-device without cloud connectivity. FlexECG's continuous passive recording overcomes the fundamental limitation of on-demand devices (smartwatches) that miss asymptomatic and nocturnal AF episodes, while its dry gold electrodes and reusable design eliminate the skin irritation (1.7% vs 15.0%) and electronic waste of single-use adhesive patches. Among all platforms evaluated, the smart ring offered the highest comfort but only PPG-level rhythm data, while the adhesive patch provided the closest clinical accuracy but with retrospective-only analysis and lower compliance. FlexECG hardware designs, edge-AI model weights (TensorFlow Lite Micro), and clinical validation data are available at <https://github.com/NTU-CardiacAI/FlexECG-2023> under MIT licence. Future work should validate FlexECG in AF screening populations (post-stroke, elderly), conduct multi-centre randomised trials comparing FlexECG-guided anticoagulation versus standard care, extend monitoring to 30 days for comparison with ILR detection yield, and integrate on-device stroke risk stratification algorithms

combining AF burden with clinical risk scores.

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Declarations

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Conflict of Interest

H. Moreau is a co-inventor on pending patent applications covering the FlexECG dry electrode design (SE2300284-4) and the edge-AI arrhythmia detection algorithm (EP23194826.9). Research materials were received from Mycronic AB. No consulting fees or equity interests are declared.

Data Availability Statement

De-identified ECG recordings, ILR-adjudicated arrhythmia labels, compliance logs, and comfort questionnaire data are available at <https://github.com/NTU-CardiacAI/FlexECG-2023> under CC BY 4.0 licence. FlexECG hardware design files (Gerber, BOM) and edge-AI model weights (TFLite Micro) are included. Raw patient data cannot be shared due to GDPR but are available upon reasonable request.

Ethical Approval

This study was approved by the Swedish Ethical Review Authority (Etikprovningensmyndigheten, Dnr 2023-02468-01) and the Karolinska University Hospital Clinical Research Board. All participants provided written informed consent. The study was registered at ClinicalTrials.gov (NCT05842466). Conducted in accordance with the Declaration of Helsinki and EU MDR 2017/745.

Appendix A

FlexECG Hardware Specifications and Edge-AI Model Architecture

This appendix provides the complete FlexECG hardware bill of materials, dry electrode fabrication process, edge-AI model architecture, and quantisation procedure for ARM Cortex-M4F deployment.

A.1 Hardware Specifications

- 1a. Substrate: flexible polyimide (Kapton 50HN, 50 μ m); dimensions 25 x 60 x 2.8 mm; weight 8.4 g (with battery)
- 1b. Electrodes: 3x dry Au (50 nm sputtered, micro-textured by O₂ plasma 100 W 2 min); diameter 10 mm; impedance 18 $\pm$ 4 kohm (dry)
- 2a. AFE: TI ADS1292R (24-bit, 500 Hz, 2-channel); CMRR >110 dB; input noise 8 μ Vpp; programmable gain 1-12x
- 2b. MCU: Nordic nRF5340 (128 MHz Cortex-M33 + 64 MHz Cortex-M1); 512 KB RAM; 1 MB Flash; BLE 5.0; 0.8 mW AI inference
- 3a. Battery: 180 mAh LiPo (Renata ICP402525); 14-day runtime at continuous 500 Hz recording + AI + hourly BLE sync
- 3b. Enclosure: IP67 medical-grade silicone overmould; magnetic USB-C charging dock; reusable >50 cycles; adhesive frame replaceable

A.2 Edge-AI Model Architecture

- 4a. Input: 10 s window (5,000 samples @ 500 Hz, single-channel); pre-processing: z-score normalisation, 0.5-40 Hz bandpass (on-chip)
- 4b. Architecture: 8 residual blocks [Conv1D(k=7) -> BN -> ReLU -> Conv1D(k=7) -> BN -> residual add]; filters 16-16-32-32-64-64-64-64
- 5a. Attention: 2-head self-attention (d_k=16) on final feature map (78 time steps x 64 channels); global average pooling -> FC 5-class softmax
- 5b. Quantisation: TensorFlow Lite Micro INT8 post-training quantisation; model size 148 KB; accuracy loss <0.3% F1 from FP32 baseline
- 6a. Inference: 82 ms per 10 s window; power 0.8 mW average (Cortex-M33 at 64 MHz); continuous real-time classification at 10 s intervals
- 6b. AF episode logic: ≥ 3 consecutive AF-classified windows (30 s) = AF episode onset; <3 consecutive non-AF windows = episode continuation