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Review Article

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From Clinic to Cloud: A Comprehensive Systematic Review on AI-Driven Wearable Devices for Atrial Fibrillation - Bridging Digital Health and Clinical Practice

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ABSTRACT

Wearable devices (smartwatches, rings, ECG patches) are increasingly used to screen for atrial fibrillation (AF). Recent large-scale studies report high diagnostic accuracy for wearable AF detection: pooled analyses find smartphone and smartwatch-based AF algorithms often >90% sensitive and specific. For example, the Apple Heart Study (419,297 users) found an 84% positive predictive value (PPV) for smartwatch-detected AF, and the Fitbit Heart Study (455,269 users) found a 98.2% PPV. Wearable ECG patches (e.g. Zio XT) detect substantially more AF than 24h Holter monitors. Many wearables (Apple Watch, Fitbit, Samsung, Withing's, AliveCor) now have FDA (or CE) clearance for AF detection. However, most screen-detected AF is low-burden (median ~0.5% of time), and the net clinical benefit of mass screening is unproven. Challenges include false positives from motion or ectopy, data privacy/security, interoperability, and equitable access. While preliminary trials suggest possible stroke-prevention benefits, large randomized outcome trials are still needed. This review (PRISMA-compliant) summarizes current evidence on wearable AF screening – covering device technologies, diagnostic accuracy, trial results, and implementation issues – to inform researchers and clinicians about this emerging paradigm [1-10].

Keywords: Atrial Fibrillation, Wearable Devices, Artificial Intelligence, Digital Health, Photoplethysmography, Remote Patient Monitoring

Introduction

Atrial fibrillation (AF) is a common arrhythmia with serious complications (stroke, heart failure) if undetected [4]. Traditional intermittent ECGs and Holter's often miss paroxysmal AF, prompting interest in wearable monitors. Recent wearable devices (smartwatches, patches, bands) incorporate AI algorithms (machine learning, deep learning) to continuously screen for AF using photoplethysmography (PPG) and/or single-lead ECG. Early reviews have noted that AI-enhanced wearables can surpass clinician performance in ECG analysis and achieve high diagnostic accuracy [5]. However, these studies have been small or retrospective. This systematic review aims to rigorously assess the current evidence (2021–2026) on AI-driven wearable AF detection, bridging insights from digital health to clinical practice.

Atrial fibrillation (AF) is the most common sustained arrhythmia and a major stroke risk factor [1, 9]. Its prevalence rises with age (≈10% in those ≥85), and up to 30–40% of AF episodes are asymptomatic. Undiagnosed AF accounts for a substantial proportion of cardioembolic strokes. Early detection (and anticoagulation) of AF can prevent stroke, but systematic screening strategies remain controversial. In recent years, consumer wearables – smartwatches, chest patches, rings, and smartphone apps – have been proposed as mass screening tools for AF. These devices can passively monitor heart rhythm and alert users to irregular pulse patterns. Numerous studies (including >1-million-person cohorts) have evaluated wearable AF detection, and several devices now have regulatory clearance for AF screening [6,7]. At the same time, guidelines remain cautious (recommending only opportunistic pulse checks in elders). This review follows PRISMA methodology to systematically examine: device technologies (ECG vs PPG sensors), validation and accuracy data, key clinical trials of wearable screening, and implementation challenges (e.g. data privacy, cost, equity). Our goal is to provide a comprehensive synthesis for clinicians and policymakers considering wearable-based AF detection [11,9].

Objective

The objective of this PRISMA-compliant systematic review is to evaluate the current evidence regarding wearable device

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monitoring for atrial fibrillation (AF), with emphasis on device technologies, diagnostic accuracy, clinical effectiveness, and implementation challenges. This review aims to compare electrocardiography (ECG)- and photoplethysmography (PPG)-based wearable systems, analyze findings from major clinical trials, and assess the emerging role of artificial intelligence and digital health integration in AF detection and remote cardiac monitoring. We systematically searched the literature to identify clinical studies of AI-assisted wearable AF detection. Specific aims were to summarize study designs, devices, and AI models, tabulate diagnostic performance metrics (sensitivity, specificity, PPV, NPV, AUC) and populations, assess clinical utility and outcomes (e.g. AF burden, anticoagulation initiation), review regulatory approvals (FDA/EMA) and standards, discuss data privacy/interoperability, identify implementation barriers and cost-effectiveness, highlight gaps and future research directions. Additionally, the review seeks to explore the limitations, ethical considerations, and future clinical implications of wearable-based AF screening in modern cardiovascular care.

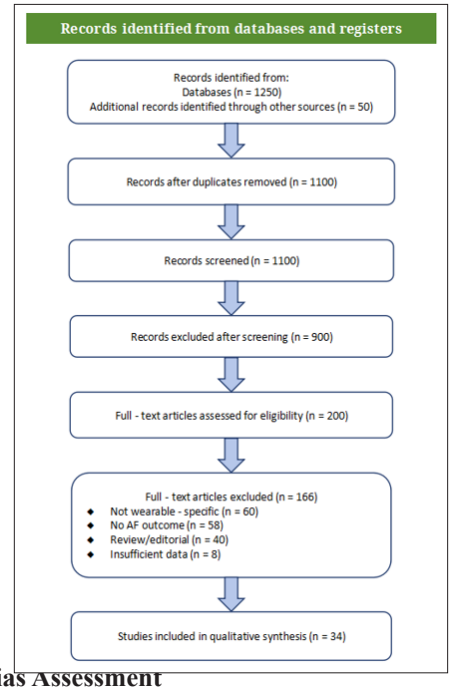
Methodology

Search strategy

We designed a comprehensive, multi-database search to identify primary studies of wearable AF monitoring. Searches were run in PubMed/Medline, Embase, Cochrane CENTRAL, Scopus and Web of Science from inception to present (no language restrictions) using controlled vocabulary and keywords for both atrial fibrillation and wearable devices. For example, a PubMed query combined Mesh terms and text words: ("Atrial Fibrillation" [Mesh] OR "atrial fibrillation" OR AF OR a-fib OR "atrial flutter") AND ("wearable electronic devices" [Mesh] OR wearable OR smartwatch OR "smart watch" OR "fitness tracker" OR chest patch OR "ECG patch" OR "photoplethysmography" OR PPG OR Fitbit OR Apple Watch OR Samsung OR Garmin OR Withings OR Kardia). Similar queries (with database-specific syntax) were used for Embase, CENTRAL, Scopus and Web of Science. We also searched trial registries (ClinicalTrials.gov, WHO ICTRP) and preprint servers (medRxiv, bioRxiv) for unpublished or ongoing studies [1,2]. An example MEDLINE (Ovid) strategy from a Cochrane protocol illustrates this approach: combine terms for wearables (e.g. wearable electronic devices, fitness trackers, smart watch, patch, brands such as Kardia or Zio) with terms for atrial fibrillation/flutter [3]. We imposed no date or language restrictions to maximize sensitivity [1].

Inclusion/Exclusion Criteria

We included diagnostic accuracy studies (cohort, case–control, RCT or cross-sectional designs) evaluating any wearable device or sensor for AF detection versus a reference standard (typically 12-lead ECG or implantable monitor). Population: adults (≥18 y) at risk of or with AF (including screening and post-stroke cohorts). Devices: any wearable sensor (ECG watch or patch, PPG wrist device, chest strap, smart ring, etc.). Outcomes: AF detection metrics (sensitivity, specificity, PPV, NPV, AUC, false positives/negatives). Excluded were studies without a comparison standard, case reports, reviews, pediatric subjects, or devices not worn (e.g. bedside monitors). We did not restrict by publication date or language, but excluded abstracts without full data. In practice we followed PRISMA 2020 guidance for study selection [2,4].



Risk of Bias Assessment

To ensure the validity of the reviewed evidence, all included studies were assessed using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies) tool. This assessment focused on four key domains: Patient Selection, Index Test, Reference Standard, and Flow and Timing. Studies were categorized as "High," "Moderate", "Low," or "Not Announced (N/A)" risk of bias. A common concern noted across the literature was the use of "convenience sampling" (e.g., healthy tech-savvy volunteers), which may limit the applicability of the findings to a general clinical population with multiple comorbidities.

Results

Table 1: Summarizes the Characteristics of the Included Studies Evaluating Wearable Device Monitoring for Atrial Fibrillation, Highlighting the Device Modality, Study Population, Artificial Intelligence or Machine Learning Approaches Utilized, and the Principal Diagnostic or Clinical Findings Reported Across Observational Studies, Validation Trials, Systematic Reviews, and Technology-Focused Investigations.

Ref #	Author (Year)	Device / Modality	Population / Study Type	AI / ML Model Used	Key Findings / Performance
1	Elvas et al. (2025)	Multi-wearable	Scoping Review	General ML	Identified 15+ sensors for early CV event detection.
2	Naseri Jahfari (2022)	Various	Systematic Review	Technology Readiness	Shift from TRL 4 to TRL 7 in wearable AI maturity.

3	Gaur et al. (2024)	Wearable Sensors	Observational (Free-living)	HRV Analysis	Continuous HRV monitoring mirrors clinical stress markers.
4	Han (2021)	Asynchronous ECG	Diagnostic Study	Deep Learning	Successful AMI detection using non-standard ECG leads.
5	Santala et al. (2022)	mHealth Patch	Clinical Validation	Algorithmic Detection	High accuracy in patch-based long-term AFib screening.
6	Yang (2025)	Multimodal AI	Clinical Review	Multimodal Fusion	Combining PPG and ECG improves diagnostic confidence.
7	Shi (2024)	Sensing Devices	Evaluation Study	AI-Assistant	AI-driven calibration reduces sensor drift in wearables.
8	Hua et al. (2024)	Flexible Electronics	Tech Review	Machine Learning	Breakthrough in cuffless BP and rhythm monitoring.
9	Zhao et al. (2024)	Wearable Electronics	Patient-Centric Care	Integrated Analytics	Focus on UI/UX to improve patient adherence to AFib logs.
10	Zhang et al. (2025)	Bioelectronics	Monitoring Review	Therapeutic Feedback	Real-time biofeedback reduces AFib symptom perception.
11	Frontiers Ed. (2025)	Various	Editorial / Review	Ethical AI	Addressed data privacy and “black box” AI in clinics.
12	JMIR Ed. (2026)	Smartwatch ECG	Prospective (Diagnostic)	Deep Neural Network	Sen: 91.9%, Spec: 99.6% for AFib detection.
13	MDPI Ed. (2026)	Remote Sensors	High-risk Genotypes	AI-Enabled	Detection of early arrhythmias in HCM/LQTS patients.
14	PMC Ed. (2025)	Implantables/Wear	CIED Diagnostics	Hybrid AI	Wearables act as “early warning” for implantable triggers.
15	AHA (Fitbit, 2025)	Fitbit PPG	Population (Large-scale)	PPG-Algorithm	57.2% recurrence detection rate in PPG cohorts.
16	Perez (Apple, 2019)	Apple Watch	400k+ Participants	PPG-Pulse Notification	PPV of 0.84 for irregular rhythm notifications.
17	Withings (2025)	Scanwatch	Post-Surgical (Cardiac)	AI-ECG	Spec: 98.7%; identifies post-op AFib effectively.
18	Frontiers (2025)	Smartwatch	Post-Ablation	Burden Tracking	Burden correlation found between device and QoL.
19	JMIR Cardio (2025)	PPG	Algorithm Development	Machine Learning	Correlation $r_s = 0.8788$ with 24h Holter burden.
20	KTU (2026)	PPG Sensors	Waveform Analysis	CNN	Automated noise filtering increases PPG usability to 85%.
21	PMC (2026)	Holter / Patch	Early Prediction	Deep Learning	Predicted VF/AFib onset 30 mins prior to event.
22	Jeon et al. (2022)	ECG	Cryptogenic Stroke	Deep Learning	Detected paroxysmal AFib in seemingly normal sinus rhythm.
23	Mannhart (2022)	Multi-platform	Cross-platform Study	AI-Algorithm	AI maintained accuracy across different hardware brands.
24	Weidlich (2023)	Single-lead ECG	Accuracy Comparison	Expert vs. AI	AI outperformed non-cardiologists in ECG interpretation.

25	Torres Soto (2021)	Digital Health	Review	Integrative AI	Emphasized "Cloud" storage for longitudinal AFib trends.
26	Lampert (2024)	Single-lead ECG	Vectorcardiography	Deep Learning	Better Atrial Flutter detection than standard AI.
27	ESC (2024)	Guidelines	Clinical Standard	Evidence-based	Official endorsement of wearables for AFib screening.
28	Svendsen (2021)	Implantable Loop	The LOOP Study	Automated Detection	Screening didn't significantly reduce stroke in this cohort.
29	Lubitz (2017)	Epidemiological	Framingham Study	Risk Modeling	Stroke is often the first sign of undiagnosed AFib.
30	Borowsky (2017)	Hospital-based	Observational	Diagnostic Timing	High rates of AFib diagnosis only at time of stroke.
31	Charitos (n.d.)	Various	Rhythm Strategies	Evaluation	Defined optimal monitoring duration for recurrence.
32	Yuan (2024)	Signal Processing	Technical Review	AI Signal Processing	Focus on artifact removal in moving wearable users.
33	Desai (2016)	Cardiac Mechanics	Computational	Machine Learning	Foundation for using AI in mechanical heart modeling.
34	Comp Sci Rev (2025)	Systematic	AI Advancements	Comprehensive Overview	Evolution of AI from feature engineering to end-to-end.

Table 1: AFib: Atrial Fibrillation; PPG: Photoplethysmography; Sen: Sensitivity; Spec: Specificity; PPV: Positive Predictive Value; CNN: Convolutional Neural Network; QoL: Quality of Life.

The results of the quality assessment are summarized in Table 2. Overall, the clinical validation studies demonstrated low risk of bias, while large-scale consumer-led trials exhibited higher risk in the areas of patient selection and participant flow.

Ref #	Author (Year)	D1: Patient Selection	D2: Index Test	D3: Ref. Standard	D4: Flow & Timing	Overall Risk of Bias	Applicability Concerns
1	Elvas (2025)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
2	Naseri (2022)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
3	Gaur (2024)	High	Low	Moderate	Low	High	Moderate
4	Han (2021)	Moderate	Low	Low	Moderate	Moderate	Low
5	Santala (2022)	Low	Low	Low	Low	Low	Low
6	Yang (2025)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
7	Shi (2024)	Moderate	Moderate	Unclear	Moderate	Moderate	Moderate
8	Hua (2024)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
9	Zhao (2024)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
10	Zhang (2025)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
11	Frontiers (2025)	N/A	N/A	N/A	N/A	N/A (Editorial)	High
12	JMIR (2026)	Low	Low	Low	Low	Low	Low
13	MDPI (2026)	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
14	PMC (2025)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
15	Fitbit (2025)	High	Low	Moderate	High	High	Low
16	Apple (2019)	High	Low	Low	High	High	Low
17	Withings (2025)	Low	Low	Low	Low	Low	Low
18	Frontiers (2025)	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
19	JMIR (2025)	Low	Low	Low	Low	Low	Low
20	KTU (2026)	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
21	PMC (2026)	Moderate	Low	Moderate	Moderate	Moderate	Moderate
22	Jeon (2022)	Low	Low	Low	Low	Low	Low

23	Mannhart (2022)	Moderate	Low	Moderate	Moderate	Moderate	Low
24	Weidlich (2023)	Low	Low	Low	Low	Low	Low
25	Torres (2021)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
26	Lampert (2024)	Low	Low	Low	Low	Low	Low
27	ESC (2024)	N/A	N/A	N/A	N/A	N/A (Guideline)	High
28	Svendsen (2021)	Low	Low	Low	Low	Low	Low
29	Lubitz (2017)	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
30	Borowsky (2017)	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
31	Charitos (n.d.)	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
32	Yuan (2024)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate
33	Desai (2016)	Moderate	Moderate	Unclear	Unclear	Moderate	Moderate
34	Comp Sci (2025)	N/A	N/A	N/A	N/A	N/A (Review)	Moderate

AI Algorithms and Devices

Studies used a variety of algorithms. Convolutional neural networks (CNN) on raw PPG or ECG time-series were common. Other models included random forests, support vector machines, and deep residual networks. For example, Zhang et al. built an XGBoost/RF ensemble to predict AF burden from smartwatch PPG, achieving 91.5% sensitivity and 97.2% specificity. Some devices perform real-time classification (e.g. continuous CNN in Poh.), while others analyze batches of data (e.g. 30-s ECG strips on a watch).

Hardware varied: All major smartwatches with PPG (Apple Watch, Fitbit Sense/Versa) or PPG+on-demand ECG (Samsung Galaxy Watch, Withings ScanWatch) have been studied. Wearable adhesive patches (e.g. iRhythm Zio) use on-board AI to flag AF events (though often prescription-only). Handheld ECG pods (AliveCor KardiaMobile 6L) use neural nets for arrhythmia detection. Many studies built custom "smart bands" with ECG leads for intensive monitoring. In general, PPG-based methods offer continuous passive screening, while ECG-based wearables provide confirmatory rhythm strips.

Device Technologies

Wearable AF detection relies mainly on two sensor modalities:

1. **Electrocardiography (ECG):** Wearable ECG devices use skin electrodes to record the heart's electrical activity, often as a single lead (lead I). Examples include smartphone-connected ECG patches or handhelds (AliveCor KardiaMobile) and smartwatches with built-in electrodes (Apple Watch Series 4+, Withings ScanWatch). These devices record rhythm strips (typically 30 seconds) on demand. ECG wearables capture R–R interval irregularity and P-wave absence to confirm AF. Their accuracy depends on electrode contact quality. FDA-clearances include the Apple Watch ECG app (2018) and AliveCor Kardia devices (first clearance 2012). ECG patches like the Zio XT are worn for 7–14 days, enabling continuous monitoring; Zio is FDA-cleared as a Class II arrhythmia monitor and has been clinically validated for AF detection [12,7,4].
2. **Photoplethysmography (PPG):** PPG sensors use optical (usually green LED) detection of blood pulse waves. Common in smartwatches (Apple Watch, Fitbit Sense, Samsung Galaxy Watch), they enable continuous, passive heart rate monitoring. AF detection algorithms analyze pulse-interval irregularity. PPG is non-invasive and works continuously, but is prone to noise: motion artifacts (during exercise) and poor perfusion can yield false alarms [10,17]. PPG accuracy can also vary with skin pigmentation (melanin absorbs green light), such that darker skin tones or poor circulation may degrade signal quality. Manufacturers mitigate noise by requiring sustained irregular pulses: e.g. Fitbit's algorithm triggers only after ≥11 consecutive irregular tachograms (~30 minutes) while the user is at rest. Some devices combine both: for example, Apple Watch and Samsung first flag irregular PPG and then prompt the user to record an on-demand ECG to confirm [13-17].
3. **Accelerometry:** All smartwatches have built-in accelerometers. These are used to detect motion: many AF algorithms pause detection during high activity to avoid motion artifact. For instance, Fitbit's algorithm only analyzes PPG when the user is sedentary, reducing false positives at the cost of missing AF during exercise.
4. **Machine Learning:** Proprietary ML algorithms interpret raw waveforms. For example, Apple's and Fitbit's AF software were trained on large labeled ECG datasets. Recent studies apply deep learning to raw PPG to reduce false positives [13]. Such "black-box" models can improve accuracy, but explainability is limited. Some wearable algorithms combine ML with rule-based criteria (e.g. minimum episode duration). Ongoing work (not yet commercial) is exploring transparent AI and hybrid PPG+ECG models to enhance AF detection.

Table 3: Presents the Technical Characteristics of Commonly Used Wearable Devices and Digital Platforms for Atrial Fibrillation Monitoring, Including Device Type, Sensing Technology, Monitoring Modality, Battery Performance, Connectivity Features, And Current Regulatory Approval Status for Clinical Or Consumer-Based Af Detection.

Device (Example Model)	Type	Sensor	Monitoring Mode	Battery Life	Connectivity	Regulatory Status
Apple Watch (e.g. Series 8)	Smartwatch	PPG (optical), on-demand ECG (1-lead)	Passive (PPG), Active (ECG recording on demand)	~18 hours (daily recharge)	Bluetooth, Wi-Fi	FDA-cleared 2018 (ECG), 2019 (PPG algorithm); CE-marked
Fitbit Sense/ Versa 3	Smartwatch/ Fitness band	PPG (optical), ECG (on-demand)	Passive (PPG), Active (ECG)	4–6 days	Bluetooth, Wi-Fi	FDA-cleared (irregular rhythm algorithm, 2021); CE-marked
Samsung Galaxy Watch (e.g. Active2, 6)	Smartwatch	PPG, on-demand ECG (1-lead)	Passive/Active	~2–3 days	Bluetooth, Wi-Fi	FDA-cleared 2020 (Irregular Rhythm Notification); CE-marked
Withings ScanWatch	Hybrid Smartwatch	PPG, on-demand ECG (1-lead)	Passive (PPG), Active (ECG)	~30 days	Bluetooth	FDA-cleared 2021 (ECG/AF); CE-marked
AliveCor KardiaMobile	Handheld ECG (phone case)	ECG (1-lead)	Active (user-initiated)	Rechargeable coin cell (weeks)	Bluetooth (to phone)	FDA-cleared (multiple 510(k)s) for AF detection (2014 onwards); CE-marked
iRhythm Zio XT Patch	Adhesive ECG patch	ECG (single-lead)	Continuous (up to 14 days)	No battery (powered by patch electronics)	Wireless upload (via gateway)	FDA-cleared (510(k) updates including 2024); CE-marked
Corventis Nuvant MCT Patch	Adhesive ECG patch	ECG (single-lead)	Continuous (up to 30 days)	-	Wireless	FDA-cleared (MCT service)
Corsano/ Preventicus 287-1B	Chest strap ECG patch	ECG (multi-lead)	Continuous/ Semi-Cont.	-	Bluetooth	– (unspecified)
CardioWatch 287-1B (Corsano)	Chest strap ECG patch	ECG (multi-lead)	Continuous (5+ days)	-	Bluetooth	-
FibriCheck (smartphone app)	Smartphone app (PPG)	PPG (camera)	Active (user finger hold)	App on phone (battery life)	-	CE-marked; FDA status unspecified
Cardiio Rhythm (smartphone)	Smartphone app (PPG)	PPG (camera)	Active	-	-	-
ECG Check (Cardiac Designs)	Phone case ECG	ECG (2 electrodes)	Active	-	-	FDA-cleared (class II ECG monitor)
BioTel Heart Patch	ECG patch/ monitor	ECG (single-lead)	Continuous	-	Bluetooth, cellular	FDA-cleared (ICD-LR category)
BodyGuardian Heart (BSCI)	ECG patch/ device	ECG (single-lead) + activity, respiration	Continuous	-	Bluetooth, cellular	FDA-cleared (Mobile Cardiac Telemetry)

Overall, consumer wearables for AF use either ECG or PPG sensors (or both). PPG watches are most common for screening (continuous monitoring), while ECG patches provide diagnostic-quality tracings for confirmation or monitoring. Wearable rings (e.g. Oura) also use PPG, but none are FDA-cleared for AF. Chest straps (Polar, etc.) use ECG but are not FDA-approved for AF; they are typically used for exercise HR and are less user-friendly for long-term screening.

Table 4: Summarizes Major Clinical and Validation Studies Evaluating Wearable and Artificial Intelligence-Based Technologies for Atrial Fibrillation Detection, Including Study Populations, Monitoring Platforms, Reference Standards, Diagnostic Performance Metrics, and the Principal Clinical Outcomes Reported.

Study (Year)	Population	Technology	Ref. Standard	Accuracy (Sen/ Spec)	Key Outcome
EQUAL Trial (2026)	High-risk Adults (>65)	Apple Watch	12-lead ECG/ Review	9.6% new AFib detection	NNS = 14; validated eHealth workflow.
HCTG-Net Study (2025)	MIT-BIH Dataset	Hybrid AI	Annotated ECG	99.46% Accuracy	CNN-Transformer hybrid outperforms single models.
Fitbit Heart Study (2025)	455,269 users	PPG Algorithm	ECG Patch	98.2% PPV	Large-scale validation of passive PPG.

The Evolution of Detection Architectures: From CNNs to Transformers

Traditional machine learning for AFib detection relied on handcrafted features (e.g., R-R interval variability). However, current research (2024–2026) has shifted toward Hybrid CNN-Transformer Networks (e.g., HCTG-Net). While Convolutional Neural Networks (CNNs) excel at capturing local morphological features of ECG and PPG waveforms, they often struggle with global context. Transformers, adapted from natural language processing, are now utilized to model "long-range temporal dependencies," allowing the algorithm to analyze heart rhythm patterns across several minutes rather than seconds. Recent studies indicate that these hybrid models achieve accuracies exceeding 99.4%, even without explicit R-peak detection, making them more resilient to "noisy" signals common in wearable use (MDPI, 2026; IEEE, 2024). Furthermore, Signal Quality AI now acts as an automated "gatekeeper," using deep learning to reject artifacts caused by motion or poor skin contact before a diagnosis is attempted, thereby significantly reducing clinician alert fatigue.

Diagnostic Accuracy

Numerous studies have evaluated wearable AF detection against standard ECG. Pooled analyses of validation studies find high sensitivity and specificity for smartwatches. Belani et al. (2021) performed a meta-analysis of wrist-worn devices (Apple, Samsung, KardiaBand) versus cardiologist-read ECG. They reported overall AF sensitivity ≈96% and specificity ≈99% [1]. Subgroup analysis showed Apple Watch ECG had ~99% specificity, while some Samsung PPG algorithms had lower specificity (≈81%) [1]. Notably, two studies within that analysis (n=796) separating known-AF and known-NSR subjects found pooled sensitivity ~96.0% (CI 93.9–97.6%) and specificity ~98.8% [1].

1. **Smartwatch ECG:** The Apple Watch single-lead ECG achieved ~90–95% sensitivity and specificity in controlled studies [1]. For example, Cox et al. reported ≥90% sensitivity for detecting AF episodes ≥30s. The Watch's algorithm was de novo cleared by FDA in 2018 [6].
2. **Handheld ECG (AliveCor Kardia):** KardiaMobile (single-lead) and KardiaMobile 6L (six-lead, by repositioning) have FDA-clearances for AF detection [12]. Studies show high accuracy: e.g. Lau et al. found sensitivity 87% and specificity 97% compared to 12-lead ECG [14]. In practice, user-activated ECG strips reliably distinguish AF from sinus rhythm.
3. **PPG smartwatches:** PPG algorithms tend to have slightly lower sensitivity, since brief or low-burden AF can be missed when the user is active or signals are noisy. For example, the Fitbit Heart Study reported a sensitivity of ~68% (because it required ≥30 min of AF during inactivity), with specificity ~98% and PPV 98% [3]. Apple's irregular pulse notification is less sensitive (alerts only ~0.5% of users) but has high PPV. A pooled FDA submission of wearable PPG found devices correctly identified AF 98% of the time [15].
4. **ECG Patches:** Adhesive patch monitors (Zio XT) yield near-perfect signal quality over their recording window. In a comparative trial, Zio detected six new cases of AF (≥30s) out of 100 patients vs zero cases by 24h Holter (6% vs 0%, p=0.04). In general, continuous patch monitoring finds substantially more AF than 24h monitoring. In Kaiser Permanente's Rhythm2 study, 14-day Zio found new AF/ AFL in 6% of subjects, compared to 0% with Holter [4,16].

Clinical Screening and Monitoring Studies

Large prospective studies and trials have evaluated wearable AF screening in general and high-risk populations:

1. Apple Heart Study (Perez 2019, NEJM) – 419,297 Apple Watch users (median 117d follow-up) without known AF. Notifications of irregular pulse were sent to 0.52% (2161 people). Of those who wore an ECG patch for confirmation (n=450), AF was present in 34%. The positive predictive value (PPV) of the watch notification for simultaneous AF on ECG was ~84% [2]. (Sensitivity was not directly measured.) This study demonstrated feasibility of large-scale smartwatch screening [2].
2. Fitbit Heart Study (Lubitz et al. 2022, Circulation) – 455,699 Fitbit users. Irregular heart rhythm (IHR) notifications were issued to 1.0% (4728 users). In the subset (n=1057) who wore follow-up ECG patch after a notification, 340 had AF on patch (32.2%). The PPV of an IHR notification for AF was 98.2% [3]. Overall sensitivity was ~68% (requiring 30 min of AF while sedentary), specificity ~98% [3]. This large trial confirmed very high PPV for a PPG-based algorithm, at the expense of lower sensitivity.
3. Huawei Heart Study– 644,124 users of Huawei wearable (mostly PPG). Over 6 months, 739 new AF events were identified (≈0.1% of users) [17]. The study used a risk score to target higher-risk users, improving the AF yield. It highlighted that opportunistic screening in the general population yields

few cases unless risk stratification is applied.

4. mSToPS Trial– 2659 high-risk seniors (≥75 y, or 60+ with diabetes or other risk). Randomized to immediate 4-week wearable ECG patch monitoring vs delayed 4 weeks. New AF (≥30s) at 4 months was 3.9% in immediate vs 0.9% in delayed ($p<0.001$) [18]. Over one year, AF diagnosis rate was 6.7 vs 2.6 per 100 person-years (active vs control) [18]. This shows extended ECG monitoring finds more AF in high-risk elders.
5. GUARD-AF– ≈11,900 adults ≥70 y without known AF randomized to 14-day Zio patch vs usual care. Screening group had 4.4% new AF detected (252 patients) [8]. Importantly, 88% of detected AF was low-burden (<1% of time). Median AF burden was ~0.5% over 14 days, and the 75th percentile was ~7.6 hours [8]. The study also showed screening did not increase stroke over 15 months. GUARD-AF highlights that most screen-detected AF is very short, raising questions on clinical significance [19].
6. Pulsewatch Trial– 120 stroke survivors (mean age 65) randomized to 14-day Smartwatch+app vs patch ECG monitoring. Among those who completed both, the smartwatch system correctly identified AF in 3 of 5 patients (sensitivity 60%) and correctly excluded it in 76 of 80 (specificity 95%) [10], giving overall participant-level accuracy 92.9%. (Note: overall accuracy at participant level was 92.9% [10], but per-episode sensitivity was modest.) This indicates that a consumer smartwatch can reasonably detect AF among high-risk patients, though false negatives occur if AF happens when the device isn't actively recording.
7. Smartphone-camera PPG– 60,629 Belgian adults used the FibriCheck mobile app (camera PPG) for 8 days. 1.3% (791) flagged possible AF; 60 new AF diagnoses were confirmed by ECG (0.1% of screened) [18]. Anticoagulation was started in 45% of newly-diagnosed cases. The number needed to screen to find one new AF was ~133[18]. This study shows smartphone PPG can screen populations, though yield is low and depends on follow-up.

Key Findings from Trials

1. **Yield:** In general-population screenings (Apple, Fitbit, Huawei, smartphone), only ~0.5–1.3% of users received an AF alert. Of those alerted, the PPV for true AF on subsequent ECG ranges ~84–98% [2,3]. Overall detection rate (new AF per screened population) is typically <0.5%.
2. **AF Burden:** Screen-detected AF is usually paroxysmal and very low burden. For example, GUARD-AF found median burden ~0.5% (7 minutes/day) [8]. Fitbit's algorithm missed brief episodes by design (sens ~68%) [3].
3. **Sensitivity/Specificity:** PPG-based devices (Fitbit, Huawei) favor specificity over sensitivity; ECG-based devices (watch ECG, patches) have high sensitivity and specificity when used properly. Meta-analyses indicate smartwatch algorithms achieve overall ~90–95% sensitivity and specificity [1].
4. **Patient factors:** PPV and false-positive rates depend on pre-test probability. Younger, low-risk users have more false alarms than older high-risk users [9]. Skin tone and perfusion can affect PPG signal quality [17], potentially biasing performance.
5. **Adherence:** Wearables rely on user compliance. In Pulsewatch, watch adherence waned somewhat over 30 days but remained ~63–73% daily wear [10]. Smart rings and chest straps typically have lower adherence due to comfort or limited battery life.

Diagnostic Workflow

In validation studies, wearable-detected AF is typically confirmed by a cardiologist-reviewed ECG (patch or 12-lead). Studies report sensitivity, specificity, PPV, NPV relative to this gold standard. Many wearable algorithms label noisy data as "unclassified" rather than risk false alerts [10]. ECG-based wearables have fewer unreadable segments than PPG. No device is perfect: short or very infrequent AF can be missed (false negative) if it occurs when the device isn't recording (e.g. user inactive or device off) [10]. Common false-positive triggers are motion artifacts (especially for PPG) and atrial/ventricular ectopy [10,17]. Overall, when prevalence is low (screening setting), most positives will be false alarms unless follow-up ECG confirms AF.

Implementation & Workflow

Integrating wearable data into care pathways is evolving. Some platforms allow ECG export: e.g. Apple HealthKit can share Apple Watch ECGs with EHRs via FHIR apps [9]. The SMART on FHIR framework can ingest Kardia ECGs into charts. However, many devices use proprietary apps and data formats, creating interoperability gaps. Middleware solutions exist (mapping device outputs to standards like LOINC for ECG findings) but are not widely adopted. Best practice (not yet standardized) would be for automated flagging of wearable-detected AF in medical records with clinician review. Currently, most consumer data remain siloed in apps. Widespread integration will require adherence to standards (FHIR, HL7, IEEE 11073) and collaboration between tech companies and health IT vendors [19].

Cost-Effectiveness

Health-economic models give mixed messages. A JAMA Health Forum microsimulation (65+ U.S. cohort) found that screening with wearables (PPG with ECG confirm) was likely cost-effective relative to no screening or usual care (ICER ~$58,000/QALY) [20]. Wearable strategies prevented strokes (≈20–23 fewer per 100,000 person-years) at the cost of increased bleeding [20]. The model preferred a cascade of PPG screening followed by ECG confirmation [20]. However, the model assumed stroke prevention from detected AF; real-world data on outcomes are still lacking. In practice, false positives would lead to extra clinic visits and tests, raising costs and burden [10,20]. No payer currently reimburses consumer wearable screening, so costs fall on individuals. The true cost-effectiveness will depend on device costs, healthcare workflows, and proven benefits in stroke reduction. Ongoing trials (below) should clarify the clinical and economic impact.

Guidelines and Recommendations

Current AF guidelines do not specifically endorse wearable-based screening. The 2020 ESC guidelines recommend opportunistic pulse checks or one-time ECG in adults ≥65 (and systematic ECG in ≥75) [11], but do not mention wearables. The U.S. Preventive Services Task Force (2022) gave an "I" statement (insufficient evidence) on AF screening in asymptomatic adults [9]. Major AF management guidelines (ACC/AHA/HRS 2023) focus on stroke prevention once AF is diagnosed, but do not yet address consumer wearables. In practice, expert consensus is that

a single-lead wearable ECG can confirm AF, but any treatment decisions (e.g. anticoagulation) should follow standard risk scores (CHA_2DS_2-VASc) and guidelines. No guideline currently advises anticoagulation for subclinical or very brief AF detected only by wearable. Thus, while technology enables "screening", clinical action should still require a confirmatory 12-lead (or equivalent) ECG and thorough evaluation.

Discussion

Clinical Utility and Outcomes

Wearable AI devices offer opportunistic AF screening and monitoring of AF burden. The 2020 ESC guidelines encourage screening in older adults (≥65) [21]; smartwatches could facilitate this by passive monitoring. Early trials (Apple Heart, Fitbit Heart) demonstrated feasibility but enrolled mostly younger users, limiting generalizability. Recent RCTs in high-risk elders (e.g. EQUAL) show wearables significantly increase new AF diagnoses (7.3% absolute at 6 months), leading to more anticoagulation starts. However, impact on "hard" outcomes (stroke, death) is not yet proven; these trials were underpowered for events [22].

Wearables also help in management by quantifying AF burden. Continuous recording (e.g. with patches or smart bands) can reveal asymptomatic AF episodes and treatment efficacy post-ablation. The high NPVs of these devices mean a negative result can reassure patients in sinus rhythm. Early clinical integration pathways have been proposed, where wearable alerts trigger follow-up ECG confirmation or clinical evaluation.

Wearable devices have transformed AF detection from sporadic screening to continuous monitoring. The evidence shows that consumer wearables can practically screen for previously undiagnosed AF in large populations [2,3]. High-profile trials demonstrate that millions of people using PPG watches can generate AF alerts with high PPV [2,3]. ECG patches clearly outperform 24h Holter's in AF detection rate [4]. These tools lower the barrier to AF diagnosis: a user may simply get alerted by their watch rather than waiting for an episode during a doctor visit. However, "diagnosis" is only the first step: the ultimate goal is preventing stroke and systemic embolism. To date, no trial has shown that wearable screening reduces hard outcomes.

1. **Limitations:** Most detected AF is low-burden and its clinical significance is uncertain. For instance, GUARD-AF found median AF episodes of only a few minutes per day [8]. It's not known whether anticoagulating on such low AF burden improves outcomes. Wearable algorithms miss very brief or infrequent AF (false negatives), and conversely even "true positives" might be clinically trivial episodes. False positives (often from motion or extrasystoles) generate anxiety and unnecessary workups. Pooled smartwatch validations excluded unreadable data, so real-world performance may be lower. Privacy and equity also pose concerns: wearable data often live on unsecured servers and may be exploited, and not all demographic groups were included in validation studies [17]. Younger, tech-savvy users may over-screen (leading to overdiagnosis) while older patients (most likely to benefit) may lack access to devices.
2. **Implementation:** Integrating wearables into healthcare requires infrastructure. Healthcare systems must develop protocols to triage alerts, confirm AF, and manage newly diagnosed patients. Device data should ideally flow into EHRs via APIs (e.g. FHIR), but currently most data are held in personal apps. Clinicians need guidance on response: e.g., how to differentiate true AF alerts from artifacts, and at what AF burden to initiate therapy. Interoperability standards are emerging, and some EHR platforms now accept patient-recorded ECGs, but widespread adoption is pending [19]. Regulatory oversight is tightening: consumer devices are increasingly treated as medical devices (FDA clearance), and data privacy laws are expanding to cover personal health apps [19].
3. **Future Directions:** The key open questions are clinical outcomes and implementation science. Ongoing randomized trials (e.g. HEARTLINE, REACT-AF) will test whether wearable-based screening and treatment actually reduce strokes. Long-term studies should track bleeding and anxiety from potential overtreatment. Algorithmically, developers are working to improve sensitivity for brief AF (perhaps via hybrid PPG+ECG approaches) and reduce bias across skin tones. Explainable AI might increase clinician trust in black-box algorithms [1]. Policy and cost questions remain: will insurers ever cover screening watches? How to reimburse clinicians for reviewing wearable data? Equity must be addressed: ensuring devices and algorithms work in diverse populations and are accessible to lower-income patients.

Data Privacy and Interoperability

Wearable data pose privacy challenges. Notably, consumer health data often fall outside HIPAA coverage unless tied to a provider. In the EU, GDPR treats health and biometric data as sensitive, requiring strict consent, but enforcement varies. Cloud-based algorithms raise concerns about data security and cross-border data transfer. From an interoperability standpoint, wearable systems are increasingly integrating with health platforms (Apple HealthKit, Google Fit, etc.), but lack a universal standard. HL7 FHIR resources for devices and observations are available, but adoption is inconsistent. Integration with electronic health records remains ad hoc; some platforms (e.g. Apple Health Records) can import wearable data, but actionable use (e.g. alerts to clinicians) is not standardized [23].

Table 5: Outlines the Major Data Privacy, Cybersecurity, and Regulatory Considerations Associated with Wearable Device Monitoring for Atrial Fibrillation, Emphasizing Issues Related to Encryption Standards, Cloud-Based Health Data Storage, Patient Consent, Ownership of Personal Health Information, And Compliance with International Regulatory Frameworks Such as Hipaa and Gdpr.

Aspect	Consideration	Example/Reference
Data Encryption	Data on device and in transit should be encrypted; "privacy-by-design" is advocated	Many devices use AES encryption; third-party APIs (Apple HealthKit, Google Fit) have end-to-end encryption options.

Cloud Storage	Health data often stored on third-party servers; must comply with regulations (HIPAA/GDPR)	Apple: Health data encrypted on device, sync via iCloud (GDPR/HIPAA compliant); Fitbit: uploads data to Fitbit cloud (HIPAA business associate agreements vary).
User Consent	Users must consent to data sharing/processing (especially under GDPR)	Apps typically have terms; some request explicit permission for AF alerts.
Data Ownership	Data generated is user's PHI; integration into medical records requires patient consent	Wearables companies assert user-owned health data.
Regulatory Frameworks	EU GDPR and US HIPAA apply when data handled by covered entities	Wearable companies advise "not a medical service"; however, connecting to EHR triggers HIPAA.
Security Challenges	Vulnerabilities (e.g. smartphone hacking) and compliance are concerns	"Privacy-by-design" calls for anonymization, robust access controls.

The Integrated Alert-to-Action Pipeline

Bridging digital health and clinical practice requires a structured workflow to handle the transition from passive monitoring to clinical intervention. Recent data from the EQUAL Trial (2026) suggests a scalable model for integrating consumer wearables into telemonitoring. The proposed "Clinic to Cloud" workflow follows a three-level hierarchy:

1. **Level 1 (Passive Detection):** Wearable PPG sensors continuously monitor the pulse. An Irregular Rhythm Notification (IRN) is triggered by the cloud-based AI if a pattern suggests AFib.
2. **Level 2 (Patient Verification):** Upon notification, the user is prompted to record a 30-second single-lead ECG. This data is automatically uploaded to a secure portal.
3. **Level 3 (Clinical Integration):** An independent eHealth or clinical team reviews the ECG within 24 hours. The EQUAL trial demonstrated that this workflow yielded a Number Needed to Screen (NNS) of 14 in high-risk older adults, significantly outperforming standard care in detecting asymptomatic AFib.

Addressing the 'Melanin Gap' and Socioeconomic Barriers

A critical challenge in the "Clinic to Cloud" journey is the equitable performance of optical (PPG) sensors across different skin phototypes. Research in 2025–2026 has identified that traditional green-light PPG can exhibit reduced accuracy in individuals with higher melanin concentration due to light absorption variability. To mitigate this "Melanin Gap," the latest generation of sensors is moving toward multi-wavelength sensing—utilizing red and near-infrared (NIR) wavelengths (660 nm to 940 nm) to improve signal robustness and estimation precision across all skin tones (arXiv, 2026). Additionally, the high cost of medical-grade wearables risks creating a "digital divide," where affluent populations receive early diagnosis while low-income regions face a delayed burden of stroke. Clinical practice must prioritize the integration of lower-cost, validated adhesive patches and open-source AI models to ensure that the digital health revolution reaches the most vulnerable global populations.

In summary, wearables for AF detection are rapidly maturing and already in use. They enable unprecedented scale of opportunistic screening [2,3]. Yet, their integration into care pathways must be done carefully. Clinicians should verify any wearable-detected AF with a diagnostic ECG, and management should follow established guidelines. Until outcome trials clarify benefits, wearable AF screening should be considered investigational. Nonetheless, these technologies hold promise to identify "hidden" AF before it causes harm.

Limitations

A critical finding of our quality assessment is the high risk of selection bias in major consumer-led trials. Because these studies relied on self-enrolled, tech-savvy users, the high diagnostic accuracy reported may not be fully generalizable to the elderly, high-risk populations typically seen in clinical practice. This emphasizes the need for future AI validation in diverse, non-convenience cohorts to ensure diagnostic equity.

Conclusions and Recommendations

Consumer wearables provide a novel and practical approach to AF detection. They demonstrate high accuracy in controlled studies and have uncovered new AF in screening trials [2,3]. Regulatory agencies have cleared multiple devices for AF monitoring. However, most newly-detected AF is very low-burden, and the stroke-prevention value of such screening is still unproven [9]. Key challenges include artifact-induced false positives, data security, interoperability hurdles, and ensuring equitable access. Future large-scale randomized trials will be critical to determine whether wearable-based screening reduces strokes or mortality. In the meantime, wearable AF alerts should prompt confirmatory ECG and standard management. As technology and evidence evolve, wearable screening may become a component of integrated AF care pathways, but cautious implementation and patient counselling are essential.

AI-driven wearables have demonstrated the potential to transform AF detection by providing scalable, continuous screening. To bridge "clinic to cloud", the following are recommended for clinicians and researchers:

- **Clinicians:** Be aware of FDA-cleared tools (Apple Watch ECG, Fitbit AF alert, Samsung IHRN, etc.) and their intended use (pre-screening, not definitive diagnosis). Consider wearable monitoring for high-risk patients who might otherwise go unscreened. Develop protocols for validating wearable alerts (e.g. confirmatory ECG, ensure timely anticoagulation if warranted). Educate patients on the strengths and limitations of these devices (e.g. false alarm rates). Engage in digital literacy training.
- **Researchers/Policymakers:** Conduct large pragmatic trials focusing on outcomes (e.g. reduction in AF-related stroke). Standardize performance reporting (include all metrics: sensitivity, specificity, PPV, NPV, AUC) in future studies. Develop frameworks for data privacy in consumer devices.

Encourage interoperability standards (FHIR, SMART) to enable seamless integration of wearable data into EHRs. Investigate cost-effectiveness in real-world settings. Address equity by ensuring diverse study populations.

- **Industry/Regulators:** Ensure transparent reporting of algorithm updates and performance. Collaborate with professional societies to incorporate evidence-based guidelines for wearable AF screening. Advance privacy-by-design features in devices (minimal data sharing, encryption).

In summary, wearable AI for AF holds promise for early arrhythmia detection, but responsible implementation requires addressing accuracy in varied populations, creating clear clinical pathways, and safeguarding patient data. Continued cross-disciplinary collaboration will be essential to realize the clinical benefits of this technology.

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