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Smartwatch-Based Electrocardiogram Detection of Atrial Fibrillation

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Abstract

Background

Atrial fibrillation (AF) is the most common treated cardiac arrhythmia in the United States, contributing substantially to morbidity, mortality, and healthcare costs. AF is associated with significant complications, including ischemic stroke and heart failure, and often occurs in patients with underlying cardiovascular risk factors such as hypertension, diabetes, and structural heart disease. Given its variable presentation, from asymptomatic to life-threatening, early detection remains a critical component of effective management. The widespread adoption of wearable technologies has introduced new opportunities for scalable, noninvasive AF screening in the general population.

Objective

This review aims to evaluate the role of smartwatch-based electrocardiogram (ECG) technologies in the detection of atrial fibrillation, with a focus on device functionality, regulatory considerations, and current evidence regarding diagnostic performance.

Methods

A narrative review of the literature was conducted, synthesizing data from regulatory documents, clinical validation studies, and publicly available manufacturer specifications. Key areas of focus included smartwatch ECG technology, photoplethysmography (PPG)-based rhythm detection, US Food and Drug Administration (FDA) regulatory pathways, and reported sensitivity and specificity of commercially available devices.

Results

Smartwatches from major manufacturers, including Apple, Samsung, and Withing's, incorporate PPG and single-lead ECG capabilities to detect irregular heart rhythms and classify episodes as sinus rhythm, atrial fibrillation, or inconclusive. These devices have received FDA clearance as Class II medical devices or software as a medical device (SaMD), enabling over-the-counter use for AF screening. Reported diagnostic performance varies, with sensitivity and specificity estimates of approximately 85% and 75% for Apple and Samsung devices, and 58% and 75% for Withing's devices. Despite their accessibility and scalability, limitations include incomplete detection of short-duration AF episodes, potential for inconclusive readings, and reliance on user engagement. Additionally, evolving software algorithms raise ongoing regulatory and cybersecurity considerations.

Conclusions

Smartwatch-based ECG technologies represent a promising adjunct for the early detection of atrial fibrillation, offering a widely accessible and user-friendly screening tool. However, these devices are not intended to provide definitive diagnoses and should be integrated into clinical care with appropriate patient education and confirmatory testing. While current evidence supports their potential utility, further independent validation studies and long-term outcome data are needed to clarify their role in improving cardiovascular outcomes and reducing healthcare burden.

Keywords

Atrial fibrillation; Smartwatch; Wearable devices; Electrocardiogram; Photoplethysmography; Digital health; Mobile health; Arrhythmia detection; FDA; Software as a medical device.

Introduction

Atrial fibrillation (AF) is the most common type of treated heart arrhythmia affecting over 12 million people in the United States [1]. AF was the underlying cause of 28,037 deaths out of 232,030 in 2021 [1]. Individuals with AF, on average, experience a total healthcare costs increase of US $27,896 in the inpatient, outpatient and emergency room compared to those without AF [2]. Risk factors to developing AF increase with age and often presents in patients with cardiovascular (CV) risk factors, structural heart disease, and comorbidities- such as, hypertension, coronary artery disease, heart failure, diabetes, and obstructive sleep apnea [3]. Given that atrial fibrillation (AF) ranges from asymptomatic presentations to life-threatening complications, including cardiogenic shock and ischemic stroke [3], timely detection and management are critical to reducing morbidity and mortality.

In response to the need for timely atrial fibrillation detection, major technology companies, including Apple Inc., Samsung Electronics, and Withing's, have developed wearable devices as scalable screening tools. In the United States, Apple holds approximately 58.3% of the mobile vendor market share, followed by Samsung (22.5%) and Google (4.5%) [4]. As of 2025, mobile phone ownership in the United States is estimated at 91%, with particularly notable growth in smartphone adoption among adults aged 50 years and older and among lower-income households [5,6]. After US Food and Drug Administration (FDA) clearance of the first smartwatch-integrated electrocardiogram (ECG) feature in the Apple Watch [7], further evaluation of its role in atrial fibrillation diagnosis is warranted.

Methods

This narrative review synthesizes current evidence on smartwatch-based electrocardiogram (ECG) technologies for atrial fibrillation detection. Relevant literature was identified through targeted searches of PubMed and Google Scholar, along with review of publicly available US Food and Drug Administration (FDA) regulatory documents and manufacturer specifications. Search terms included “atrial fibrillation,” “smartwatch,” “wearable devices,” “electrocardiogram,” “photoplethysmography,” and “FDA clearance.” Priority was given to recent clinical validation studies, comparative analyses of commercially available devices, and publications addressing regulatory considerations and software as a medical device (SaMD). Additional sources were identified through manual review of reference lists. Given the narrative nature of this review, no formal systematic inclusion criteria or quality assessment tools were applied. The goal was to provide a clinically relevant overview of device functionality, diagnostic performance, and regulatory considerations.

Functionality of Smartwatches

As of early 2026, Apple Watch models capable of running the latest watchOS and recording ECGs, include Series 6 and later, as well as all Apple Watch Ultra models [8]. The device uses a closed-circuit configuration that combines wrist-based photoplethysmography (PPG) with electrical sensors on the Digital Crown to generate a single-lead ECG comparable to a Lead I tracing. Results are classified as sinus rhythm, atrial fibrillation, or inconclusive. Inconclusive results may occur because of high or low heart rates, rhythm disturbances other than atrial fibrillation, or inadequate signal quality [9].

Other US Food and Drug Administration–cleared smartwatches for atrial fibrillation detection, including the Withing’s Scan Watch and Samsung Galaxy Watch, similarly integrate PPG and electrical sensors to produce single-lead ECG recordings [Table 1; 10-13]. Yet, functional differences exist. Withing’s devices use an OLED display of an analog watch without touchscreen or typing capability [Table 2; 14]. Although this simplified interface may facilitate review of physiologic data, users must access a paired smartphone to initiate certain actions or respond to notifications, which may delay urgent communication.

The Samsung Galaxy Watch incorporates an Irregular Heart Rhythm Notification feature that periodically assesses pulse irregularity using PPG and prompts users to obtain an ECG when irregular rhythm is detected [15]. However, similar to the Apple Watch [16], it does not detect all episodes of atrial fibrillation, and users with atrial fibrillation may not receive notifications. For Samsung devices, episodes lasting less than 1 hour may not trigger an alert [15].

Table 1: A. Representative examples of smartwatch ECGs in the same patient with confirmed AF. The diagnosis of AF is correctly made by each smartwatch's automated algorithm [17]. **B-D.** From left to right: ECG recordings displayed on the Apple Health App with Apple Watch, the Samsung Health Monitor application with Samsung Galaxy Watch, and the Withing's App with Withing Scan Watch [18-20].

	Apple Watch	Withings ScanWatch	Samsung Galaxy Watch
Atrial Fibrillation Detection Mode	Autonomous monitoring and user-initiated ECG recording	User-initiated ECG recording	Autonomous IHRN (Irregular Heart Rhythm Notification) and user-initiated ECG recording
Hardware	Digital smartwatch with 42mm touchscreen display	Hybrid 38mm analog watch with 16mm digital display.	Digital smartwatch with 40mm touchscreen display
Battery Life	24 – 38 hours	30 – 35 days	Up to 40 hours
Cost $(USD)^1$	$399	$370	$250
Software	watchOS 26	HealthSense OS 4	Wear OS 5
Mobile Operating System Compatibility | Application	iOS 26 | Health	iOS 16 or above or Android 12.0 or above | Withings	Android 11.0 or above | Galaxy Wearable

1 Devices included in this table are the Apple Watch Series 11, Withings ScanWatch 2, and Samsung Galaxy Watch7. For consistency, cost comparisons reflect manufacturer-listed retail prices for the smallest (or only) available size. Promotional discounts, special offers, and applicable taxes were not included.

Table 2: Key Characteristics of Selected Smartwatches with Atrial Fibrillation Detection Capability.

Regulations and Considerations

The promise of smartwatches for atrial fibrillation detection is tempered by regulatory considerations, cybersecurity challenges, and the need to align expectations between consumers and healthcare professionals [21]. Wearable devices incorporate both hardware and software components. Hardware elements, including ECG and PPG sensors, are regulated under established medical device frameworks. In contrast, software components are more complex because their algorithms may evolve over time. In the absence of a predicate device, the Apple Watch ECG feature received US FDA De Novo classification as a Class II device for rhythm analysis [7]. Samsung and Withing's devices subsequently obtained FDA clearance through the 510(k) pathway as software as a medical device (SaMD) intended for over-the-counter use [22,23]. Because SaMD platforms rely on algorithm-driven analysis, regulatory review includes evaluation of risk assessment, cybersecurity measures, data encryption, firmware updates, and protection against unauthorized access. Minor algorithm modifications require documentation, whereas substantial performance-related changes may necessitate new regulatory submissions [24]. Importantly,

these devices are cleared for atrial fibrillation detection and rhythm classification, not for definitive diagnosis, detection of other arrhythmias, or identification of myocardial infarction [22-23]. This distinction underscores the importance of clinician involvement and appropriate patient counseling.

Diagnostic Performance and Limitations

A clinical validation study reported sensitivity and specificity for atrial fibrillation detection at approximately 85% and 75% for Apple and Samsung devices and 58% and 75% for Withing's devices, respectively [25]. These limitations translate to real-world performances where false positives may lead to unnecessary anxiety and healthcare utilization, while false negatives may delay diagnosis.

Devices may fail to detect short-duration AF episodes, generate inconclusive readings due to motion artifact or poor signal quality, and depend heavily on user engagement for accurate data acquisition. Additionally, variability in proprietary algorithms and periodic software updates may further influence diagnostic consistency over time [21], highlighting the need for ongoing validation and transparency.

Discussion

Despite increasing adoption of smartwatch-based atrial fibrillation detection, several important challenges limit their current clinical impact. Variability in diagnostic performance across devices, coupled with incomplete detection of short-duration or asymptomatic AF episodes, raises concerns regarding reliability in real-world settings. Furthermore, dependence on user engagement and proper device usage introduces additional variability that may disproportionately affect older adults or individuals with limited technological literacy.

Integration of wearable-generated data into clinical workflows remains another unresolved challenge. Clinicians may face difficulties interpreting large volumes of patient-generated health data, and standardized pathways for incorporating these data into electronic health records are not yet well established. Additionally, disparities in access to smartwatch technology particularly among lower-income and underserved populations may exacerbate existing healthcare inequities.

From a regulatory perspective, the evolving nature of software as a medical device presents ongoing challenges in maintaining consistent performance while allowing iterative improvements. Greater transparency in algorithm development and standardized validation frameworks may help address these concerns.

Future research should prioritize longitudinal studies evaluating clinical outcomes, cost-effectiveness, and the impact of smartwatch-based screening on stroke prevention and overall cardiovascular morbidity. Establishing clear clinical guidelines for the use of wearable-derived data will be essential for optimizing their role in patient care.

Conclusion

Atrial fibrillation remains a prevalent and costly condition in the United States, underscoring the need for scalable strategies that facilitate earlier detection. Smartwatch-based electrocardiogram technology offers a widely accessible platform for rhythm screening, supported by regulatory clearance and growing

clinical evidence. However, these devices are best viewed as adjunctive tools rather than replacements for traditional diagnostic methods. Effective integration into clinical practice requires patient education, appropriate interpretation of results, and confirmatory testing when indicated. Continued research and post market surveillance will be critical in defining their long-term clinical value and role in cardiovascular care.

Key points

- Smartwatch-based ECG technologies enable scalable atrial fibrillation screening.
- Diagnostic accuracy varies across devices, with moderate sensitivity and specificity.
- Devices are FDA-cleared for detection but not for definitive diagnosis.
- Clinical integration is limited by workflow challenges and data interpretation barriers.
- Further research is needed to evaluate long-term outcomes and health system impact.

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