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ARTIFICIAL INTELLIGENCE (AI)–ENABLED WEARABLES FOR CARDIAC RHYTHM MONITORING: DIAGNOSTIC PERFORMANCE, REGULATORY TRENDS, AND CLINICAL INTEGRATION.

Supreet Kaur *

Staff Biomedical Engineer, Wayne State University, Detroit, MI.

* Corresponding Author

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ABSTRACT

Wearable technologies extend cardiac-rhythm monitoring beyond conventional clinical settings. Smartwatches, handheld single-lead electrocardiogram (ECG) devices, adhesive ECG patches, chest straps, rings, and remote-monitoring platforms increasingly use artificial intelligence (AI) and machine-learning methods to detect atrial fibrillation (AF), classify rhythm abnormalities, assess signal quality, prioritize ambulatory recordings, and estimate arrhythmia burden. This review examined the technological, regulatory, diagnostic, and clinical-integration considerations relevant to AI-enabled wearable cardiac monitoring. This review evaluates evidence concerning wearable ECG and photoplethysmography (PPG)-based rhythm-monitoring technologies, with attention to diagnostic performance, regulatory authorization, algorithmic limitations, and requirements for safe clinical implementation.

Wearable ECG devices can identify AF with high sensitivity and specificity in selected and supervised populations. However, diagnostic performance varies according to device modality, recording quality, patient characteristics, AF prevalence, reference standard, software version, and the handling of inconclusive or unclassifiable recordings. PPG-based irregular-rhythm notifications can provide useful screening signals but do not independently establish an AF diagnosis because they detect pulse irregularity rather than cardiac electrical activity. In contrast, interpretable wearable ECG recordings may provide rhythm documentation when incorporated into an appropriate clinical evaluation pathway.

Regulatory authorization defines a device's permitted intended use but does not establish universal diagnostic accuracy, generalizability, clinical-outcome benefit, or suitability for autonomous clinical decision-making. Effective implementation requires external validation; transparent reporting of unclassifiable recordings; clinician-overread and confirmatory ECG pathways; governance of algorithm updates; privacy and cybersecurity protections; and ongoing post-market performance monitoring. AI-enabled wearable rhythm monitoring is most likely to improve care when used to support, rather than replace clinical judgment.

Keywords: Artificial intelligence (AI); Atrial fibrillation (AF); Wearable devices; Ambulatory ECG; Photoplethysmography; Remote Patient Monitoring; Digital Health; Machine learning.

1 INTRODUCTION

Atrial fibrillation is the most common sustained cardiac arrhythmia and is associated with stroke, heart failure, hospitalization, reduced quality of life, and mortality. AF is often intermittent or asymptomatic, making it difficult to capture during a short in-clinic ECG recording. Conventional monitoring approaches, including Holter monitors, event monitors, mobile telemetry, and implantable cardiac monitors, remain central to diagnosis but may be limited by monitoring duration, cost, access, and patient burden [1,2].

Wearable technologies are expanding opportunities for repeated, prolonged, and patient-initiated rhythm assessment outside traditional healthcare settings. Smartwatches and rings may passively identify pulse irregularity using PPG, whereas smartwatches and handheld devices can acquire single-lead ECG recordings. Adhesive ECG patches can record continuously for days or weeks, allowing detection of intermittent or asymptomatic arrhythmias that may not be captured through short-duration clinical monitoring [3–5].

The increasing volume of wearable physiologic data has created a role for AI and machine-learning methods. These methods may support rhythm classification, beat detection, artifact reduction, signal-quality assessment, AF episode segmentation, arrhythmia-burden estimation, and prioritization of recordings for clinician review. However, the clinical value of wearable-AI systems depends on input-signal quality, validation methodology, the intended-use population, the reference standard, and the presence of a safe pathway for clinical review and follow-up [3,4]. This review examines AI-enabled wearable rhythm-monitoring technologies, with emphasis on AF detection, diagnostic performance, regulatory context, workflow design, and responsible clinical implementation.

2 MATERIALS AND METHODOLOGY

2.1 Review design and reporting framework

This study used a structured narrative review design to synthesize evidence on AI-enabled wearable technologies for cardiac rhythm monitoring. The review addressed wearable sensing modalities, AI-based signal analysis, diagnostic performance for AF detection, regulatory considerations, and clinical implementation.

The review was informed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 statement to improve transparency in reporting information sources, search concepts, eligibility criteria, source selection, and evidence synthesis. PRISMA 2020 principles were used as a reporting framework; this article was not designed or conducted as a formal systematic review or meta-analysis [2]. No protocol was preregistered. Screening and data extraction were not independently conducted in duplicate, and no formal risk-of-bias or GRADE certainty-of-evidence assessment was performed. Findings should therefore be interpreted as a structured narrative synthesis.

2.2 Information sources and search strategy

Relevant evidence was identified through iterative searches of PubMed-indexed literature, U.S. Food and Drug Administration resources, professional-society publications, and reference lists from key reviews and primary studies. Regulatory information was obtained from FDA resources concerning AI-enabled medical devices and sensor-based digital-health technologies [5,6].

Search concepts combined terms related to wearable rhythm monitoring, AI, AF detection, diagnostic accuracy, remote monitoring, and regulation. Representative search terms included “wearable ECG,” “single-lead ECG,” “ambulatory ECG,” “smartwatch,” “smart ring,” “photoplethysmography,” “atrial fibrillation,” “artificial intelligence,” “machine learning,” “diagnostic accuracy,” “patch monitor,” “remote patient monitoring,” “FDA,” and “digital health.”

The search prioritized contemporary evidence while retaining landmark studies of smartwatch screening, wearable ECG interpretation, continuous ECG patch monitoring, and remote rhythm-management pathways [4,11–16].

2.3 Eligibility criteria and source selection

Sources were eligible if they reported diagnostic performance of wearable devices for AF or other rhythm abnormalities; AI- or machine-learning-assisted analysis of wearable ECG or PPG signals; regulatory information concerning AI-enabled or sensor-based wearable devices; or clinical workflow, governance, and implementation evidence.

Included device categories were smartwatches, handheld ECG devices, adhesive ECG patches, chest straps, smart rings, fitness trackers, and remote-monitoring platforms. Eligible source types included professional guidelines, regulatory documents, systematic reviews, primary diagnostic-accuracy studies, and clinical implementation studies. Sources were excluded if they addressed only nonwearable 12-lead ECG systems, cardiac imaging AI, noncardiac monitoring, or signal-processing studies without clinically interpretable rhythm outcomes.

Titles and abstracts were screened for relevance, with full-text assessment of potentially eligible sources. Duplicate reports were removed before full-text review. A PRISMA 2020 flow diagram should be included before submission after insertion of the verified number of records identified, duplicates removed, reports screened, full texts assessed, exclusions with reasons, and sources included [2].

2.4 Data extraction and Synthesis

Information was extracted, where available, on device category, sensing modality, monitoring duration, AI function, study population, AF prevalence, reference standard, sensitivity, specificity, predictive values, area under the receiver operating characteristic curve, and the proportion of interpretable, inconclusive, rejected, or unclassified recordings. Further extraction domains included clinician-overread pathways, confirmatory-testing procedures, regulatory intended use, algorithm-version control, privacy, cybersecurity, and data-governance considerations. Evidence was synthesized narratively because of heterogeneity in device hardware, software versions, signal modalities, decision thresholds, study populations, rhythm definitions, monitoring duration, and reference standards.

3 RESULTS AND DISCUSSION

3.1 Wearable Monitoring Technologies and AI Functions

Wearable rhythm-monitoring technologies differ in sensing modality, monitoring duration, degree of user interaction, and clinical role. Smartwatches, handheld ECG devices, adhesive ECG patches, chest straps, and rings can acquire either pulse-derived or electrical signals as shown in Figure 1. Devices using PPG assess pulse irregularity, whereas wearable ECG devices record cardiac electrical activity. AI may support signal-quality assessment, rhythm classification, episode segmentation, AF-burden estimation, and triage for clinical review [3,4].



Figure 1: Wearable rhythm-monitoring modalities.

Smartwatches, handheld ECG devices, ECG patches, chest straps, and smart rings vary in their sensing modality, monitoring duration, and suitable clinical role. Devices may use PPG, ECG, or both. AI may support signal-quality assessment, rhythm classification, and triage of recordings for clinician review.

Table 3.1: Wearable rhythm-monitoring modalities

Device category	Typical signal	Primary role	Important limitation
Smartwatch	PPG, with optional single-lead ECG in selected devices.	Passive irregular-pulse screening and intermittent ECG capture.	Motion artifact, intermittent sampling, false alerts
Handheld ECG	Single-lead or multi-lead ECG.	Patient-triggered rhythm documentation.	Requires user activation and adequate recording technique
ECG patch	Continuous single-lead ECG.	Extended ambulatory arrhythmia detection.	Limited-lead information and potentially delayed review.
Chest strap	Electrical or pulse-derived signal.	Exercise and ambulatory rhythm monitoring.	Motion, skin-contact, and adherence effects.
Smart ring or fitness tracker	Usually, PPG.	Passive pulse-irregularity screening.	Does not independently provide diagnostic ECG evidence.

PPG detects changes in peripheral blood volume and can estimate pulse rate and pulse-to-pulse irregularity. PPG-based systems can identify patterns compatible with AF but are susceptible to motion artifact, poor sensor contact, low peripheral perfusion, ectopy, and non-AF cause of pulse irregularity [7]. Wearable ECG devices record cardiac electrical activity directly. Smartwatch ECG functions and handheld ECG devices usually provide short, patient-triggered single-lead recordings. ECG patches can provide continuous monitoring over several days or weeks and may capture paroxysmal or asymptomatic arrhythmia missed by brief monitoring periods [8,9].

3.2 AI Applications

AI can support wearable rhythm monitoring through:

- Automated classification of sinus rhythm, possible AF, tachycardia, bradycardia, and unclassified recordings.
- Signal-quality assessment and artifact identification.
- Beat detection and R–R interval analysis.
- Segmentation of potential arrhythmia episodes from long-duration ECG data.
- Estimation of AF burden.
- Triage of recordings for clinician review.
- Integration of longitudinal wearable data with symptoms, medication use, and remote-monitoring workflows [3,4].

For multiday ECG patch recordings, AI-assisted triage may reduce manual-review burden by flagging potentially meaningful events. However, clinician overread remains important for artifact, borderline recordings, atrial flutter, frequent ectopy, short supraventricular tachycardia, and algorithmically unclassified outputs.

3.3 Screening versus diagnosis

PPG-based irregular-rhythm alerts should be interpreted as screening outputs. They may identify individuals who require further ECG assessment but do not independently establish AF because they do not document cardiac electrical activity [1,2].

An interpretable wearable ECG may provide rhythm documentation when reviewed by a qualified clinician. Current professional guidelines require ECG documentation to establish a diagnosis of AF. Wearable notifications should therefore be communicated as possible rhythm abnormalities requiring confirmation rather than as definitive diagnoses.

4 DIAGNOSTIC PERFORMANCE AND CLINICAL INTEGRATION

4.1 AF-detection performance

Large observational studies have demonstrated the feasibility of smartwatch-based AF screening. The Apple Heart Study evaluated irregular-pulse notifications in more than 400,000 participants and showed that consumer wearable technology can identify individuals for confirmatory assessment [10,11]. Studies of smartwatch ECGs, handheld ECG

devices, ECG patches, and other wearable technologies frequently report favorable sensitivity and specificity for AF detection, particularly in supervised or selected populations compared with reference ECG recordings [13–16,18]. Systematic reviews and meta-analyses similarly report generally high diagnostic performance for wearable ECG technologies, although estimates vary by device, population, study design, and approach to indeterminate recordings [19–21].

Diagnostic performance should not be generalized automatically across wearable platforms. Accuracy depends on the hardware, signal modality, AI algorithm, software version, recording environment, patient characteristics, AF prevalence, rhythm definition, decision threshold, and reference standards.

4.2 Inconclusive and unclassified recordings

A major limitation of wearable rhythm monitoring is the occurrence of inconclusive, unreadable, rejected, or algorithmically unclassified recordings. These outcomes may result from motion artifact, poor skin contact, low-amplitude signals, insufficient recording duration, ectopy, irregular rhythms other than AF, or limitations in the algorithm.

Excluding unclassified recordings from diagnostic analyses may increase reported sensitivity and specificity while overestimating real-world performance. Studies should report the proportion of interpretable, inconclusive, rejected, and unclassified recordings; reasons for non-classification; and diagnostic performance before and after exclusion of poor-quality traces [19–21].

4.3 Prevalence and predictive value

Positive predictive value is strongly influenced by AF prevalence in the monitored population. Even highly specific algorithms may generate substantial numbers of false-positive alerts when deployed in low-prevalence settings, including younger consumer populations without established cardiovascular risk factors. This limitation does not remove the potential value of wearable screening. Rather, it emphasizes the importance of appropriate target populations and efficient confirmatory pathways.

4.4 Clinical workflow

A safe wearable-monitoring pathway may include the following sequence:

- A wearable device detects pulse irregularity or classifies an ECG as possible AF.
- The patient records a high-quality wearable ECG when possible.
- A clinician reviews the tracing or arranges confirmatory ECG testing.
- If uncertainty persists, extended ambulatory ECG monitoring is considered.
- Treatment decisions incorporate confirmed rhythm diagnosis, AF burden, symptoms, stroke risk, bleeding risk, comorbidities, and patient preferences.

Extended patch monitoring and remote-monitoring strategies may be especially useful for patients with intermittent symptoms, cryptogenic stroke, elevated AF risk, post-ablation follow-up needs, or a requirement for longitudinal rhythm assessment as shown in the illustrative ECG waveform and AF demonstrates irregular R–R intervals and the absence of organized P waves as shown in Figure 2. [4,18–21].

4.5 Illustrative ECG waveforms

Sinus rhythm simulated demonstrates regular R–R intervals and visible P waves preceding QRS complexes. AF demonstrates irregular R–R intervals and the absence of organized P waves. These waveforms are illustrative schematics and do not represent patient recordings.

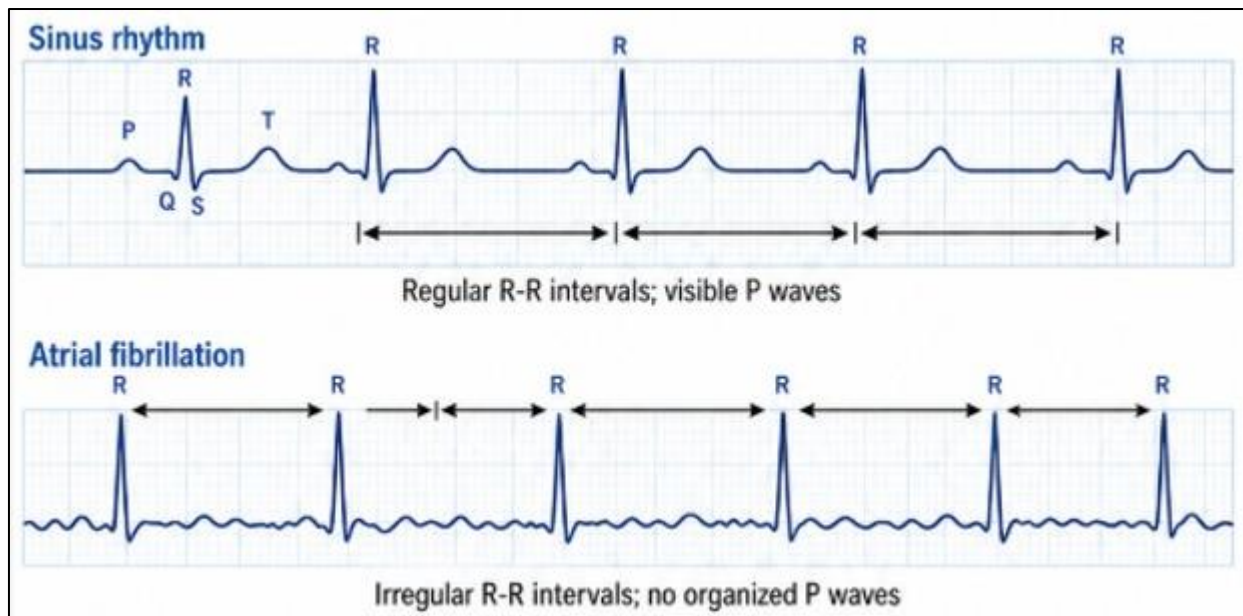


Figure 2: Illustrative single-lead ECG waveforms

4.6 Quantitative evaluation of wearable-AI performance

Diagnostic accuracy and operational usability should be reported together when evaluating wearable-AI rhythm classifiers. In addition to sensitivity and specificity, studies should report predictive values, AF burden, and unclassified-recording rates [19–21].

For a binary classifier, where TP , TN , FP , and FN represent true positives, true negatives, false positives, and false negatives, respectively, sensitivity is:

$$\text{Sensitivity} = \frac{TP}{TP + FN}$$

Sensitivity represents the proportion of reference-standard AF recordings correctly identified by the wearable device or AI algorithm.

Specificity is:

$$\text{Specificity} = \frac{TN}{TN + FP}$$

Specificity represents the proportion of non-AF recordings correctly classified as non-AF.

Positive predictive value and negative predictive value are:

$$\text{PPV} = \frac{TP}{TP + FP}$$

$$\text{NPV} = \frac{TN}{TN + FN}$$

Unlike sensitivity and specificity, predictive values are influenced by AF prevalence in the monitored population. This is particularly important for consumer-device deployment in low-risk populations.

The F1 score provides a harmonic mean of sensitivity and positive predictive value:

$$F_1 = 2 \times \frac{\text{PPV} \times \text{Sensitivity}}{\text{PPV} + \text{Sensitivity}}$$

For continuous wearable ECG monitoring, AF burden can be calculated as:

$$\text{AF burden (\%)} = \frac{\sum_{i=1}^n d_i^{AF}}{T_{\text{analyzable}}} \times 100$$

where d_i^{AF} is the duration of the i -th confirmed AF episode and $T_{\text{analyzable}}$ is the total analyzable monitoring duration.

The rate of unclassified recordings should be reported separately:

$$\text{Unclassified-recording rate (\%)} = \frac{N_{\text{unclassified}}}{N_{\text{total recordings}}} \times 100$$

This metric should not be omitted, because exclusion of unclassified traces may artificially improve reported diagnostic performance.

R–R interval variability can be represented using the coefficient of variation:

$$CV_{RR} = \frac{\sigma_{RR}}{\mu_{RR}}$$

where σ_{RR} is the standard deviation and μ_{RR} is the mean of R–R intervals. Increased R–R variability may contribute to AF detection but can also result from ectopy, artifact, or other arrhythmias.

A generic machine-learning classifier may be expressed as:

$$P(AF | \mathbf{x}) = \text{sigmoid}[f_{\theta}(\mathbf{x})]$$

where $\mathbf{x}$ represents wearable-derived input features, f_{θ} represents the trained model, and $P(AF | \mathbf{x})$ represents the estimated probability of AF.

4.7 Human oversight

AI may be most useful as a triage system rather than as an autonomous diagnostic system. Algorithms can prioritize recordings for clinician review, but clinicians remain responsible for interpretation, confirmation, communication, and treatment decisions.

Healthcare organizations should define alert recipients, review processes, response-time expectations, escalation thresholds, documentation practices, and responsibility for patient follow-up. Without a defined workflow, wearable monitoring may create excessive alerts, delayed communication, increased clinician burden, and uncertainty regarding accountability.

5 REGULATORY, GOVERNANCE, AND FUTURE CONSIDERATIONS

5.1 Regulatory context

FDA authorization, clearance, or approval establishes that a device may be marketed for a specified intended use [5,6]. Health systems should evaluate more than regulatory status before implementing a wearable-AI platform. Important criteria include:

- The authorized intended use and target population.
- The sensing modality and monitoring duration.
- The specific AI function performed.
- The validation dataset and reference standard.
- External validation across relevant demographic and clinical subgroups.
- False-positive, false-negative, and unclassified-recording rates.
- Algorithm-version control and software-update governance.
- Privacy, cybersecurity, data ownership, and interoperability.
- Clinician-overread and confirmatory-testing pathways.
- Ongoing post-market safety and performance monitoring.

5.2 Equity and Data governance

Wearable monitoring may improve access to rhythm assessment for some patients while exacerbating disparities for others. Access is influenced by device cost, smartphone availability, digital literacy, internet connectivity, language, disability, and trust in healthcare systems.

Wearable technologies also generate longitudinal physiologic data requiring robust governance. Health systems should establish policies addressing informed consent, data retention, cybersecurity, access control, interoperability, alert management, data ownership, and medico-legal responsibility.

5.3 Future Directions & Research

Future research should move beyond isolated diagnostic-accuracy studies and evaluate implementation, clinical utility, and patient-centered outcomes. Priority areas include prospective external validation across diverse demographic, clinical, and care-setting populations; standardized reporting of uninterpretable, unclassified, and algorithm-inconclusive recordings; and head-to-head evaluation of ECG- and photoplethysmography (PPG)-based approaches for specific clinical tasks.

Studies should also assess the validity and reproducibility of AI-derived AF-burden estimates against appropriate continuous ECG reference standards, including how burden estimates vary with device wear time, signal loss, artifact, intermittent sampling, algorithm version, and analytic definitions of an AF episode. Comparative evaluations should report both per-recording diagnostic performance and intention-to-diagnose performance that accounts for recordings the device cannot classify.

Additional implementation priorities include evaluation after software and algorithm updates; clinician-review workload, alert burden, and time to diagnostic confirmation; interoperability with electronic health records; patient understanding and adherence; privacy and cybersecurity safeguards; and equity in performance, access, and downstream care. FDA lifecycle recommendations emphasize that manufacturers should monitor post-market performance and identify changes in device inputs, use context, or real-world performance that could alter device safety or effectiveness. Randomized or pragmatic trials should determine whether wearable-AI monitoring improves outcomes that matter to patients and health systems, rather than merely increasing AF detection.

Relevant outcomes include time to confirm diagnosis, appropriate anticoagulation when indicated, stroke and systemic-embolism outcomes, healthcare utilization, quality of life, anxiety related to alerts, clinician workload, false-positive downstream testing, and cost-effectiveness. These studies should be designed to distinguish beneficial earlier detection from overdiagnosis, unnecessary testing, or treatment triggered by low-burden arrhythmia findings of uncertain clinical significance.

6 CONCLUSION

AI-enabled wearable technologies are expanding cardiac-rhythm monitoring by enabling repeated, prolonged, and patient-centered assessment outside conventional healthcare settings. Their immediate clinical value may include screening for possible AF, capturing intermittent symptomatic rhythm disturbances, extending ambulatory ECG monitoring, supporting estimation of arrhythmia burden when validated against suitable reference standards, and prioritizing recordings for clinician review. Wearable-AI performance is not a fixed property of a device category. It depends on the specific device and sensor modality, input-signal quality, target population, clinical task, reference standard, software version, analytic threshold, and approach to unclassified recordings. High reported sensitivity and specificity do not eliminate important practical challenges, including artifact, incomplete or uninterpretable recordings, false alerts in low-prevalence populations, variable generalizability, and the need for confirmatory ECG evidence. PPG-based irregular-rhythm notifications should be understood primarily as screening or triage signals because they identify pulse irregularity rather than directly record cardiac electrical activity. When a diagnosis is needed, ECG-based documentation and clinical review are preferred; professional guidance recommends confirmation of PPG-detected arrhythmias using a 12-lead ECG when feasible or another ECG-based device when a conventional ECG cannot capture the episode. The appropriate standard for adoption is therefore not whether a system is labeled AI-enabled or has regulatory authorization. Wearable rhythm-monitoring systems should demonstrate transparent, externally validated, task-specific performance in their intended-use population and be embedded within clinically supervised pathways for interpretation, confirmation, follow-up, privacy and cybersecurity protection, algorithm-change governance, and ongoing post-market monitoring. AI is most likely to improve rhythm care when it augments clinical judgment and helps direct limited clinical attention toward recordings and patients most likely to benefit from timely evaluation.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

Disclosure of conflict of interest

There is no conflict of interest.

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