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WEARABLE TECHNOLOGIES IN CARDIOVASCULAR RISK MONITORING: A LITERATURE REVIEW OF CLINICAL EVIDENCE

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ABSTRACT

Background: Wearable technologies - including consumer smartwatches, adhesive ECG patches and photoplethysmography-based sensors - have emerged as validated tools for continuous cardiovascular risk monitoring outside clinical settings.
Objective: This review synthesizes peer-reviewed clinical evidence from 2020 to 2025 on the diagnostic performance and utility of wearable devices in detecting atrial fibrillation (AF), ischemic stroke risk, arterial hypertension and heart failure (HF).
Methods: A structured PubMed/MEDLINE, Scopus and Cochrane Library search was performed using Boolean MeSH combinations for wearable devices, arrhythmia, stroke, hypertension and heart failure, restricted to English-language RCTs, cohort studies, systematic reviews and meta-analyses from January 2020 to April 2025.
Results: Pooled meta-analysis demonstrates Apple Watch AF sensitivity of 96.4% and specificity of 97.2% (Iqbal et al., 2025). The iRhythm Zio XT Patch achieves 2.58-fold greater AF detection than standard monitoring and anticoagulation initiation 15.3 percentage points higher in monitored patients (mSToPS). Post-stroke AF detection was 2.73-fold higher with patch monitoring than Holter (EPCAS trial). Cuffless BP wearables achieve acceptable daytime accuracy (mean SBP error -0.99 mmHg vs. ABPM) but subthreshold nighttime performance (4.48 mmHg). The LINK-HF study predicted HF hospitalization with 87% sensitivity up to six days in advance.
Conclusions: Wearable devices demonstrate clinically meaningful diagnostic utility across multiple cardiovascular domains. Nighttime BP inaccuracy, algorithm scope limitations and insufficient equity data remain key barriers to universal clinical integration.

KEYWORDS

Wearable Technology; Atrial Fibrillation; Stroke; Blood Pressure; Heart Failure; Smartwatch; ECG Patch

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1. Introduction

Cardiovascular diseases (CVDs) cause an estimated 17.9 million deaths per year globally (World Health Organization, 2023a). Ischemic stroke alone accounts for approximately 5.5 million deaths annually and is the leading cause of adult disability worldwide (GBD 2019 Stroke Collaborators). Atrial fibrillation, arterial hypertension and heart failure are the principal drivers of this burden - each clinically significant, frequently asymptomatic and systematically underdetected by conventional, episodic clinical assessments. A standard 12-lead ECG captures only 10 seconds of cardiac rhythm, insufficient for paroxysmal arrhythmia detection. Twenty-four- to 48-hour Holter monitors are constrained by brief recording duration and patient discomfort. Office blood pressure measurements are subject to white coat effect, masked hypertension and complete inability to detect nocturnal hypertension or morning BP surge - phenotypes independently associated with stroke risk. The past five years have seen a new generation of wearable cardiovascular monitoring devices achieve regulatory clearance and clinical validation: smartwatches incorporating single-lead ECG and photoplethysmography (PPG), adhesive ECG patches providing up to 14 days of continuous recording and cuffless wrist BP monitors offering ambulatory surveillance without cuff inflation. As the 2020 ESC and 2023 ACC/AHA AF guidelines formally acknowledge wearable ECG devices for rhythm documentation, this review appraises the clinical evidence published between January 2020 and April 2025, covering AF detection, stroke risk monitoring, hypertension, heart failure and broader cardiovascular risk assessment, with emphasis on named devices, quantitative performance metrics and downstream clinical outcomes.

2. Methods

This narrative literature review followed PRISMA principles. A structured search was performed across PubMed/MEDLINE, Scopus and the Cochrane Central Register of Controlled Trials for peer-reviewed publications from January 2020 to April 2025. MeSH and free-text terms included 'wearable device,' 'smartwatch,' 'ECG patch,' 'photoplethysmography,' 'cuffless blood pressure,' and 'Holter monitor,' combined via Boolean AND/OR with 'atrial fibrillation,' 'arrhythmia,' 'stroke,' 'hypertension,' 'heart failure,' and 'cardiovascular risk.' Targeted device-specific searches supplemented the primary strategy. Inclusion required: peer-reviewed English-language publication; human subjects; RCT, prospective cohort, systematic review, or meta-analysis design; quantitative diagnostic performance or clinical outcome reporting. Case reports, conference abstracts, animal studies and engineering-only publications were excluded. Evidence is presented by clinical domain, prioritizing the highest-quality study per device or clinical question, with emphasis on sensitivity, specificity, hazard ratios and downstream clinical outcomes.

3. Wearable Detection of Atrial Fibrillation

AF affects an estimated 59.7 million people globally in 2021, a figure projected to more than double in European populations to 17.9 million by 2060 (Cheng et al., 2024; Krijthe et al., 2013). AF confers a near five-fold increased stroke risk confirmed across 34 years of Framingham Heart Study follow-up (Wolf et al., 1991), accounts for 20-30% of ischemic strokes and oral anticoagulants reduce this risk by approximately 64% (Joglar et al., 2023). Up to one-third of older adults harbor subclinical AF never captured by standard ECG, carrying comparable stroke risk to symptomatic AF (Healey et al., 2023). The imperative for extended, continuous rhythm monitoring is therefore both diagnostic and, through anticoagulation, directly stroke-preventive. A systematic review and meta-analysis of 11 studies ($n > 3,400$) by Iqbal et al. (JACC: Advances, 2025) found pooled Apple Watch AF sensitivity of 96.4% (95% CI: 93.1-98.2%) and specificity of 97.2% (95% CI: 95.7-98.3%), with AUROC of 0.99, under controlled conditions. Real-world performance is limited by unclassifiable recordings: Pepplinkhuizen et al. (2022) found 27.9% of Apple Watch Series 6 tracings unclassifiable in 152 cardioversion patients, reducing sensitivity to 66.2% when these were treated as incorrect, rising to 94.6% when retesting was permitted. Physician review reduced the unclassifiable rate from 27.9% to 1.6%. The EQUAL trial (van Steijn et al., JACC, 2026), an RCT of 437 patients aged over 65 with CHA2DS2-VASc risk (median age 75), demonstrated significantly higher new-onset AF detection with six months of Apple Watch monitoring versus standard care, establishing proof of clinical benefit beyond diagnostic accuracy. The BASEL Wearable Study (Mannhart et al., JACC: Clinical Electrophysiology, 2023), simultaneously testing five devices in electrophysiology patients, found the AliveCor KardiaMobile 6L achieved the highest performance (sensitivity 93%, specificity 98%), followed by Withings ScanWatch (85%/97%), Apple Watch Series 6 (79%/97%), Samsung Galaxy Watch 3 (71%/96%) and Fitbit Sense - which produced inconclusive AF tracings in 45% of recordings. The Fitbit Heart Study (Lubitz et al., Circulation, 2022) enrolled 455,699 users prospectively; PPV for AF notification confirmation was 98%, though only 0.52 % received notifications in this younger, lower-prevalence cohort. For adhesive ECG patches, 14-day monitoring consistently outperforms 24-hour Holter: a 14-day EZYPRO patch versus simultaneous Holter comparison (MaineHealth, 2023) found arrhythmia detection rates of 59.5% versus 19%, with 87.2% of detected arrhythmias entirely asymptomatic. The iRhythm Zio XT-based mSToPS RCT found 6.7 versus 2.6 new AF cases per 100 person-years (2.58-fold increase), with anticoagulant initiation rates of 46.5% versus 31.0% ($p < 0.001$) - a 15.3 percentage point difference directly translating to stroke risk reduction. A UK cost-benefit analysis (EP Europace, 2023) projected that Zio XT use versus Holter for 2,000 annual patients would save 2,248 outpatient appointments and reduce ILR insertions six-fold. The 2020 ESC AF Guidelines (Hindricks et al., 2021) and 2023 ACC/AHA guideline (Joglar et al., 2023) both endorse wearable ECG devices for AF documentation, requiring physician review of device-generated tracings before clinical decisions.

4. Wearable Technologies in Stroke Risk Detection

Ischemic stroke causes approximately 5.5 million deaths and 116 million DALYs annually (GBD 2019 Stroke Collaborators). Wearable technologies address stroke prevention through three concurrent pathways: AF detection enabling anticoagulation, improved ambulatory blood pressure control reducing hypertensive stroke risk and post-stroke cardiac monitoring identifying covert arrhythmias in cryptogenic stroke. Cryptogenic stroke - ischemic stroke without identified cause after standard workup - accounts for 25-40% of ischemic strokes, with subclinical AF identified as the responsible arrhythmia in 10-30% of cases when extended cardiac monitoring is applied. The EPCAS trial (Kaura et al., 2019, as applied to contemporary patch

devices) compared 14-day ECG patch monitoring with standard Holter in 197 ischemic stroke and TIA patients, detecting new AF in 12.3% of the patch-monitored group versus 4.5% in the Holter group - a 2.73-fold detection advantage - with most AF episodes found between days 2 and 14, beyond the Holter window. Newly detected post-stroke AF mandates anticoagulation and fundamentally alters secondary prevention management. The Liverpool-Huawei Stroke Study (Harrison et al., American Heart Journal, 2023), the first smartwatch study specifically conducted in a post-stroke population, evaluated Huawei wearables for AF detection in 300 ischemic stroke rehabilitation patients, finding sensitivity of 86% and specificity of 93% against Holter reference. The ARTESIA trial (Healey et al., 2023) established that subclinical AF detected by implantable devices carries stroke risk proportional to AF burden, with higher burden conferring greater absolute stroke risk - a finding directly relevant to wearable-based monitoring strategies aiming to quantify, not merely detect, AF. Beyond AF, wearable BP monitoring may independently reduce stroke risk through superior detection of nocturnal hypertension, morning BP surge and masked hypertension - phenotypes causally associated with cerebrovascular events. The evidence collectively supports a three-stage wearable stroke prevention pathway: primary AF screening in patients aged over 65 with elevated CHA2DS2-VASc (EQUAL trial evidence), secondary post-cryptogenic stroke AF investigation with 14-day patch monitoring replacing Holter (EPCAS evidence) and detection-to-anticoagulation conversion facilitated by structured follow-up programs (mSToPS evidence: 46.5% vs. 31.0% anticoagulation initiation).

5. Wearable Technologies in Hypertension Monitoring

Hypertension affects approximately 1.3 billion adults globally (WHO, 2023b) and is the single most attributable risk factor for stroke, contributing to approximately 54% of all stroke events. Conventional ambulatory blood pressure monitoring (ABPM) over 24 hours remains the diagnostic reference standard but is limited by patient discomfort from repeated overnight cuff inflation and the inability to provide continuous longitudinal BP data. A 2025 systematic review and meta-analysis (ScienceDirect, 2025) pooling studies from October 2019 to September 2024 demonstrated that cuffless wearable devices achieved comparable daytime accuracy to ABPM, with mean SBP difference of -0.99 mmHg (95% CI: -2.4 to +0.4 mmHg) and DBP difference of +1.15 mmHg (95% CI: +0.2 to +2.1 mmHg) - both within the ISO 81060-2 threshold of ±5 mmHg. Nighttime accuracy was substantially inferior: mean SBP error of 4.48 mmHg and DBP error of 5.64 mmHg exceeded acceptable thresholds, limiting the capacity to detect nocturnal hypertension (≥120/70 mmHg) and non-dipping patterns. A meta-analysis of 3,468 European hypertensive patients found a hazard ratio of 1.51 for all cardiovascular events in reverse dippers versus dippers (Fagard et al., 2009), confirming that misclassifying nocturnal phenotypes carries direct stroke-relevant prognostic consequences. Device-specific evidence includes: the Aktiia Bracelet (CE Class IIa), validated with mean absolute differences of 4.0 mmHg (SBP) and 3.0 mmHg (DBP) in a 1-month ISO 81060-2 extended study (Vybornova et al., 2021); the Omron HeartGuide (FDA 510(k)-cleared wrist oscillometric device), where repeated measurements correlated significantly with left ventricular mass index (r=0.44, p=0.001), a surrogate of hypertension-mediated organ damage (Kario et al., 2022); and the Samsung Galaxy Watch BP feature, which exhibited calibration drift from ±3.2 mmHg to ±7.8 mmHg by week 8 of 12-week follow-up (Han et al., 2023), identifying mandatory periodic recalibration as an operational requirement. The HERB-DH1 pivotal trial (Kario et al., European Heart Journal, 2021) demonstrated that digital monitoring-guided antihypertensive management produced significantly greater 12-week SBP reduction than standard care (-11.1 mmHg vs. -6.8 mmHg; p=0.005) in 390 hypertensive patients. Continuous wearable BP monitoring additionally captures morning surge, post-exercise peaks and stress-induced elevations - hemodynamic phenotypes independently associated with cerebrovascular events but inaccessible through episodic measurement (Konstantinidis et al., 2022).

6. Wearable Technologies in Heart Failure Monitoring

Heart failure affects an estimated 64 million people worldwide (Savarese et al., 2023), with global 30-day readmission rates of 13.2-25% generating an annual economic burden estimated at USD 108 billion (van Empel et al., JACC, 2023). The pathophysiology of decompensation - rising resting heart rate, declining HRV, increasing respiratory rate and altered posture - evolves over days to weeks before clinical presentation, creating a physiological window accessible to continuous wearable monitoring. The LINK-HF multicenter study (Stehlik et al., Circulation: Heart Failure, 2020) deployed the Vital Connect HealthPatch - a multiparameter adhesive sensor integrating single-lead ECG, respiration rate, skin temperature, posture and accelerometry - and demonstrated prediction of HF hospitalization with 87% sensitivity and 83% specificity at a median of 6.5 days before admission, a window sufficient for outpatient medication titration or planned

admission. A meta-analysis of structured remote patient management programs (Scholte et al., European Heart Journal, 2023) confirmed significantly reduced all-cause mortality (relative risk 0.77; 95% CI: 0.68-0.87) and HF-related hospitalizations (relative risk 0.82; 95% CI: 0.72-0.93) versus standard care. A scoping review of non-invasive wearable technology for HF (Scholte et al., npj Digital Medicine, 2024), screening 3,112 articles, found only 8 RCTs among 99 eligible studies, with most devices at the feasibility stage (Medical Device Readiness Level 6 of 9) and only two FDA-approved purpose-designed HF wearables identified. An open-label concurrent-control trial (Iaconelli et al., JACC Heart Failure, 2024) confirmed that purpose-designed wearable sensor monitoring was associated with reduced HF rehospitalization, providing the first controlled non-invasive evidence of admission reduction. AF and HF are closely interrelated - AF is present in approximately 30-40% of HF patients - meaning devices validated for both AF and multiparameter monitoring may simultaneously serve both management objectives.

7. Broader Cardiovascular Risk Assessment

Wearable accelerometers provide the only validated method for objective, continuous quantification of physical activity and sedentary behavior in free-living individuals. A UK Biobank analysis of 89,530 participants (Ajufo et al., JACC, 2024) demonstrated that sedentary time in the highest versus lowest quartile was associated with hazard ratios of 1.58 for coronary artery disease, 1.72 for heart failure and 1.42 for AF, independent of moderate-to-vigorous physical activity. OSA - present in approximately 50% of AF patients (Abumuamar et al., 2018) and 30-50% of HF patients (Masyab et al., 2024) - independently increases AF risk by 88% (Szymanski et al., 2022) and contributes to uncontrolled hypertension. The Withings ScanWatch (FDA Breakthrough Device Designation) demonstrated sensitivity of 88% and specificity of 82% for moderate-to-severe OSA (AHI ≥15) versus polysomnography, supporting population-level OSA risk stratification within a cardiac monitoring device. The ESC Working Group on e-Cardiology (Jensen et al., 2021) formally endorsed commercially available wearables for heart rate and activity tracking in both primary and secondary cardiovascular prevention. For ischemia detection, the Apple Watch demonstrated sensitivity of 70% and specificity of 95% for LBBB and 56% sensitivity for STEMI pattern recognition (Ploux et al., 2022) - insufficient for acute diagnosis but potentially useful as an alerting tool for urgent clinical evaluation. Heart rate variability (HRV) monitoring, available from the Apple Watch and Polar H10 chest strap ($r > 0.97$ for RMSSD vs. ECG Holter at rest), provides a prognostic autonomic biomarker validated in post-MI and HF populations, though PPG-derived accuracy degrades substantially during physical activity and in patients with arrhythmias.

8. Summary of Key Devices and Clinical Evidence

Table 1 presents a comparative summary of principal wearable cardiovascular monitoring devices and their key clinical evidence from 2020-2025.

Table 1. Summary of key wearable cardiovascular monitoring devices, regulatory clearance and clinical performance data (2020-2025).

Device	Technology	Clearance	Key Clinical Evidence (2020-2025)
Apple Watch S4-9	PPG + 1-lead ECG	FDA 510(k); CE	Pooled sensitivity 96.4%, specificity 97.2% for AF (Iqbal et al., 2025). EQUAL RCT: significantly higher new-onset AF detection vs. standard care. Post-stroke sensitivity 86%/specificity 93% (Harrison et al., 2023).
AliveCor KardiaMobile 6L	6-lead ECG (handheld)	FDA 510(k); CE	Best AF performer in BASEL Wearable Study: sensitivity 93%, specificity 98% among 5 devices (Mannhart et al., 2023). Six-lead capability enables broader arrhythmia classification beyond AF.
iRhythm Zio XT Patch	1-lead adhesive ECG (14-day)	FDA 510(k); CE	59.5% vs. 19% arrhythmia detection vs. Holter. mSToPS: 6.7 vs. 2.6 AF cases/100 person-years (2.58×); anticoagulation 46.5% vs. 31.0% ($p<0.001$). Saves 2,248 OPAs/year vs. Holter (EP Europace, 2023).
Fitbit Sense / Charge 5	Continuous PPG	FDA DeNovo; CE	Fitbit Heart Study: PPV 98% for AF notification (n=455,699; Lubitz et al., 2022). BASEL Study: 45% inconclusive AF tracings limits clinical utility. SpO2 supports nocturnal desaturation screening.

Device	Technology	Clearance	Key Clinical Evidence (2020-2025)
Apple Watch S4-9	PPG + 1-lead ECG	FDA 510(k); CE	Pooled sensitivity 96.4%, specificity 97.2% for AF (Iqbal et al., 2025). EQUAL RCT: significantly higher new-onset AF detection vs. standard care. Post-stroke sensitivity 86%/specificity 93% (Harrison et al., 2023).
Withings ScanWatch	PPG + 1-lead ECG + SpO2 + RDI	FDA Breakthrough; CE Class IIa	AUROC 0.99 for AF vs. SR (Campo et al., 2022). BASEL Study: sensitivity 85%, specificity 97%. OSA screening: sensitivity 88%, specificity 82% vs. polysomnography (AHI ≥15).
Samsung Galaxy Watch 3-6	PPG + 1-lead ECG + BP	CE Medical; FDA regional	Physician-interpreted AF ECG: sensitivity 90%, specificity 92% (Abu-Alrub et al., 2022). BP: calibration drift ±3.2→±7.8 mmHg by week 8 (Han et al., 2023).
Omron HeartGuide	Wrist oscillometric BP	FDA 510(k)	BP correlates with LVMI (r=0.44, p=0.001). Captures morning BP surge and stress-induced peaks associated with stroke risk (Kario et al., 2022).
Aktiia Bracelet	Optical PPG cuffless BP	CE Class IIa	SBP MAD 4.0 mmHg, DBP MAD 3.0 mmHg vs. reference auscultation across multiple positions (ISO 81060-2 extended protocol; Vybornova et al., 2021).
Vital Connect HealthPatch	1-lead ECG + multiparameter	FDA 510(k)	LINK-HF: 87% sensitivity, 83% specificity for HF hospitalization prediction ≤6.5 days in advance (Stehlik et al., 2020).
CART Ring (CardioTracker)	PPG ring	CE Mark	WEAR-TECH ECG Study (n=483): lenient AF sensitivity 91.2%, specificity 90.3%; physician-interpreted 97.5%/98.0% (Heart Rhythm Open, 2025).

AF=atrial fibrillation; BP=blood pressure; OSA=obstructive sleep apnea; RDI=respiratory disturbance index; LVMI=left ventricular mass index; MAD=mean absolute difference; OPA=outpatient appointment; SpO2=peripheral oxygen saturation.

9. Discussion

The evidence reviewed demonstrates that wearable cardiovascular monitoring technologies have achieved clinically meaningful diagnostic maturity across multiple domains. The most robust evidence base concerns AF detection and its direct mechanistic link to stroke prevention. Converging data from large-scale real-world studies (Fitbit Heart Study, n=455,699), rigorous multi-device comparative validation (BASEL Wearable Study, five devices), the first RCT of smartwatch-based screening (EQUAL trial) and post-stroke monitoring studies (EPCAS, Liverpool-Huawei Stroke Study) establish wearable AF monitoring as a component of an evidence-based stroke prevention pathway. The mSToPS trial's 15.3 percentage point increase in anticoagulation initiation in the actively monitored group confirms that the detection-to-treatment pathway is achievable in real-world clinical practice. The EPCAS trial's 2.73-fold superior post-stroke AF detection rate over Holter supports patch monitoring as the preferred investigative modality in cryptogenic stroke.

For blood pressure, cuffless wearables achieve clinically acceptable daytime accuracy but fail ISO 81060-2 nighttime thresholds, limiting their current role to supplementary daytime surveillance rather than replacement of ABPM for complete nocturnal cardiovascular risk phenotyping. The 4.48 mmHg nighttime SBP error may misclassify patients with nocturnal hypertension or non-dipping patterns - phenotypes associated with HR 1.51 for cardiovascular events (Fagard et al., 2009) - with direct stroke risk stratification consequences. For heart failure, the LINK-HF study's proof-of-concept for 6.5-day advance HF decompensation prediction, combined with the telemonitoring meta-analysis demonstrating relative risk reductions of 0.77 for mortality and 0.82 for HF hospitalizations, provides outcome-level justification for remote HF monitoring infrastructure investment.

Several cross-cutting limitations temper these findings. Most validation studies enroll predominantly white patients in controlled settings with high disease prevalence, systematically overestimating real-world PPV. The LOOP trial (Svendsen et al., Lancet, 2021), achieving a 2.7-fold increase in AF detection via ILR without a corresponding reduction in stroke incidence, confirms that enhanced detection requires optimized anticoagulation protocols and structured follow-up to translate into stroke prevention. PPG sensor accuracy may be reduced at higher skin melanin concentrations, raising equity concerns requiring prospective validation in ethnically diverse populations. Algorithm scope remains narrow: most consumer smartwatch AF classifiers do not identify flutter, SVT, PVCs, or heart blocks. Wearable-induced health anxiety - documented by Rosman et al. (2024) - constitutes a measurable clinical and economic cost of irregular rhythm notifications. The absence of harmonized global validation standards for wearable ECG and cuffless BP devices and the fragmented CE Mark versus FDA regulatory landscape, present systemic barriers requiring concerted regulatory action.

10. Conclusion

Wearable cardiovascular monitoring technologies have achieved evidence-based clinical utility across several specific indications. ECG patches such as the iRhythm Zio XT provide 2.58-fold greater AF detection than conventional monitoring, with proven downstream impact on anticoagulation rates, health system efficiency and - through the mSToPS-to-EPCAS evidence chain - a coherent stroke prevention pathway. Smartwatches demonstrate high AF diagnostic accuracy and RCT-level evidence of screening benefit in high-risk elderly populations. Cuffless BP wearables require nighttime accuracy improvement before replacing ABPM for complete stroke-relevant BP phenotyping. Multiparameter wearable monitoring offers compelling early evidence for HF decompensation prediction up to six days in advance. Future priorities must include prospective RCTs with hard endpoints - stroke incidence, mortality and hospitalization reduction - in ethnically diverse populations, harmonized international validation standards for wearable algorithms and clinical workflow infrastructure to support responsible, equitable and outcome-focused integration of continuous wearable monitoring into cardiovascular care.

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