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RESEARCH ARTICLE

MOBILE APPS AND WEARABLE DEVICES FOR MONITORING BLOOD PRESSURE AND HEART RATE: VALIDATION AND CLINICAL APPLICABILITY

Igor Andreevich Egorov[1] , Kristina Andreevna Sadovski [2], Varvara Stanislavovna Illarionova [3], Polina Yurievna Lobach [4], Anastasia Borisovna Leonova [5], Lilya Ramilevna Shamshetdinova [6]

[1]Moscow Medical University "Reaviz", 2/2, Krasnobogatyrskaya str., Moscow, 107564, Russia ORCID: 0009-0005-8735-7495
[2]Belgorod State University, 85, Pobedy str., Belgorod, 308015, Russia ORCID: 0009-0002-5409-4981
[3]Samara State Medical University, 89, Chapaevskaya str., Samara, 443099, Russia ORCID: 0009-0000-8450-9469
[4]irogov Russian National Research Medical University, 1 Ostrovitianov str., Moscow, 117997, Russia ORCID: 0009-0001-3276-2021
[5]Pirogov Russian National Research Medical University, 1 Ostrovitianov str., Moscow, 117997, Russia ORCID: 0009-0008-4430-0140
[6]Pirogov Russian National Research Medical University, 1 Ostrovitianov str., Moscow, 117997, Russia ORCID: 0009-0005-7950-6120

*Corresponding Author

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Abstract: ***Annotation*** With the rapid development of digital healthcare, mobile apps and wearable devices are increasingly being considered as potential tools for continuous monitoring of cardiovascular parameters, including blood pressure and heart rate. Despite the widespread adoption of such technologies, significant questions remain about their metrological validity, reproducibility of data, and clinical applicability. This study provides a systematic analysis of modern solutions with an emphasis on compliance with international validation standards (ESH/ISO 81060-2, AAMI/ANSI SP10), as well as an assessment of the impact of algorithmic and technical factors on the reliability of measurements. Special attention is paid to the probabilistic characteristics of the generated data: the identification of statistical patterns indicating excessive regularity or structural uniformity, which may indicate post-processing or artificial smoothing of signals. The analysis showed that only a limited number of commercially available devices demonstrate sufficient correlation with reference methods (Pearson correlation coefficients >0.85 for systolic pressure and >0.90 for resting heart rate), with significant variability observed under conditions of physical exertion or arrhythmias. The results obtained emphasize the need for an integrated approach to the assessment of digital biomarkers, from technical validation to analysis of the context of their generation and presentation.

Keywords: Mobile applications, wearable devices, blood pressure, heart rate, validation, clinical applicability, digital healthcare, biomarkers.

INTRODUCTION

Cardiovascular diseases (CVD) still retain the status of the main cause of premature mortality and disability both in the Russian Federation and globally. According to WHO, about 18 million people die from CVD every year, and a significant proportion of deaths are associated with late diagnosis of hypertension and arrhythmias[1]. In this context, methods of early and continuous monitoring of key hemodynamic parameters, primarily blood pressure (BP) and heart rate, are of particular importance.

In parallel, there is a rapid transformation of the medical paradigm under the influence of digital technologies. The development of personalized medicine, the growing computing power of mobile devices, and the miniaturization of sensors have created the conditions for the mass adoption of wearable systems and specialized applications positioned as tools for proactive health monitoring. However, the widespread availability of such solutions does not always correlate with their scientifically proven accuracy. This problem is particularly acute when interpreting data that users can use to make independent decisions about taking medications or seeking medical help.

The present work is aimed at a critical assessment of modern mobile applications and wearable devices designed to monitor blood pressure and heart rate.

MATERIAL AND METHODS

In preparing the article on the evaluation of mobile applications and wearable devices for monitoring blood pressure and heart rate, the authors relied on a set of theoretical approaches borrowed from related disciplines, from clinical cardiology to regulatory science and biomedical engineering.

A critical review of the literature was conducted. The focus is not only on systematic reviews and meta-analyses published in Scopus and PubMed over the past five years, but also on primary validation studies performed using the ESH or AAMI protocols. The work was particularly closely analyzed, which compared the readings of commercial devices with the "gold standard" – invasive pressure measurement or 12-channel ECG. At the same time, attention was also drawn to methodological weaknesses: the small sample size, the selection of healthy volunteers without taking into account concomitant diseases, and the short duration of follow-up.

An attempt at typologization was made to streamline the variety of solutions. Unlike the formal division by platform (iOS/Android) or form of factor (watches, bracelets, clips), we proceeded from three dimensions: technological (optical, electrical, hybrid sensors), regulatory (the status of a medical device according to the classification of the FDA, CE or Roszdravnadzor) and functional – is the product intended for mass for the consumer or for use as part of the monitoring of patients with an established diagnosis. This approach, in our opinion, avoids the superficial judgment like "all smart watches are equally inaccurate."

Special attention is paid to modeling real clinical scenarios. The analysis included data on the influence of external and biological factors on signal stability, as well as the possibility of integrating the data into electronic medical systems – without this, the wearable device remains an "island of information" that does not integrate into the clinical process.

RESULT.

The modern market of solutions for noninvasive monitoring of cardiovascular parameters is represented by a wide range of devices – from mass consumer gadgets to highly specialized medical systems. The most common category remains smart watches and fitness trackers, such as the Apple Watch, Fitbit devices, or Samsung Galaxy Watch. Their popularity is explained not only by their accessibility, but also by the possibility of continuous collection of heart rate data in everyday life. However, it is important to emphasize that most of these gadgets were not originally designed as medical instruments: their algorithms are optimized for the average physiological patterns of healthy users, and not for the detection of pathologies [2].

At the same time, solutions that are positioned specifically as medical devices are also appearing on the market. A striking example is the Omron HeartGuide, a smartwatch form factor device that combines an oscillometric cuff in a bracelet case with a clinically validated blood pressure measurement method. A similar approach is used by Withings BPM Connect, which offers the user a compact blood pressure monitor with the ability to synchronize data via a mobile application. Such devices undergo a certification procedure (including registration as medical devices in the Russian Federation and FDA approval in the USA), which fundamentally distinguishes them from most "smart" gadgets.

A separate niche is occupied by mobile applications that, without their own hardware, try to use the built-in sensors of smartphones to assess hemodynamic parameters. The most common approach is photoplethysmography (PPG), in which a camera and a flash LED are used to register changes in blood supply to the capillaries in the fingertip [3]. Based on the temporal characteristics of the pulse wave, some developers claim the possibility of an indirect assessment of blood pressure. However, independent studies, including meta-analyses of recent years, show extremely low reproducibility of such measurements outside of controlled conditions. Applications that use built-in electrodes (for example, when touching the sensor on the back of a smartphone) to register a one-way ECG-like curve look more promising. This approach, implemented, in particular, in the Apple Watch and a number of third-party solutions, demonstrates high sensitivity to atrial fibrillation, although it does not replace full-fledged electrocardiography.

Modern wearable devices and mobile applications rely on several physiological and technical approaches to registering cardiovascular parameters, each of which has its own capabilities and limitations. Photoplethysmography (PPG) is the most widely used method based on recording changes in tissue light absorption during the passage of a pulse wave. With the help of an LED and a photodetector built into the body of a fitness bracelet or smartwatch, the system detects microscopic fluctuations in blood supply to peripheral vessels. The heart rate is estimated based on the peak interval, and in the presence of persistent rhythm disturbances – for example, a chaotic sequence of intervals – algorithms can signal possible atrial fibrillation. However, the accuracy of the PPG signal strongly depends on the position of the device, the level of perfusion, skin pigmentation, and motor artifacts, which limits its reliability in real conditions [4].

For direct measurement of blood pressure, most validated devices still use the oscillometric technique. Its essence lies in the registration of pressure fluctuations in the cuff during its gradual depressurization. The amplitude of these fluctuations correlates with systolic and diastolic blood pressure, and algorithms based on empirical models (often patented) calculate the final values. Although this approach requires inflating the cuff, which makes it less convenient than "contactless" solutions, it remains the most reliable non–invasive method adopted in international validation standards. That is why devices such as Omron HeartGuide or Withings BPM Core do not abandon the pneumatic element, despite the trends towards miniaturization [5].

In recent years, the field using simplified electrocardiography has also been actively developing. Some smart watches (primarily the Apple Watch, starting with the 4th generation) are equipped with electrodes on the dial and strap, which allows you to register a single-channel ECG-like signal when touched with both hands. Despite the limited number of leads, this approach demonstrates high sensitivity and specificity in detecting atrial fibrillation – in a number of studies, the rates exceed 95%. However, it does not allow the diagnosis of other types of arrhythmias or

ischemic changes, which is important to take into account when interpreting the results.

The role of artificial intelligence and machine learning methods stands out. Almost all modern systems, even seemingly simple ones, rely to one degree or another on signal post-processing algorithms: noise filtering, pulse wave segmentation, and calibration for individual user characteristics. Some developers claim that it is possible to estimate blood pressure "without a cuff" solely based on the PPG signal using neural network models. However, independent checks show that such algorithms are often trained on narrow cohorts, and their generalizing ability is sharply reduced when applied to new populations. Moreover, the "black box" of AI interpretation makes it difficult for both validation and clinical trust, especially in cases where the algorithm produces abnormal but unexplained results [6].

It is impossible to assess the reliability of mobile applications and wearable devices for monitoring blood pressure and heart rate without a clear reference to generally accepted standards and methodological frameworks. To date, the key guidelines are protocols developed jointly by the American Association for the Development of Medical Devices (AAMI), the European Society of Hypertension (ESH) and the International Organization for Standardization (ISO), in particular the ISO 81060-2:2018 standard, which regulates the procedure for clinical validation of noninvasive tonometers [7]. In Europe, the recommendations of the European Society of Cardiology (ESC) also have a significant impact, especially regarding the diagnosis of arrhythmias using digital instruments. In the United States, the regulatory role is played by the FDA guidelines, which, in addition to technical accuracy, increasingly require evidence of clinical usefulness and cybersecurity.

For clarity, Table 1 provides a comparison of key validation criteria and relevant reference methods adopted in modern practice.

Basic validation criteria and reference methods for evaluating wearable heart monitors

Parameter	The validation standard	The reference method	Acceptable deviation
Blood pressure	ISO 81060-2:2018	Office measurement by trained personnel / SMAD	The average error is less than 5 mmHg, CO is less than 8 mmHg.
Pulse rate (at rest)	IEEE 1708-2014	12-channel ECG	The error is less than 3 beats/min
Detection of AF	ESC recommendations (2021)	Holter monitoring / 12-channel ECG	Sensitivity ≥ 90%, specificity ≥ 90%
Detection of other arrhythmias	There is no single standard	Long-term ECG monitoring	It is evaluated individually according to the type of arrhythmia.

It should be noted that formal compliance with acceptable deviations does not guarantee clinical applicability. For example, the device can fit within ± 5 mmHg on average, but systematically underestimate systolic pressure in elderly patients with stiff arteries, which is especially dangerous in the high–risk group. That is why modern approaches increasingly insist on stratified validation: separately for age groups, genders, BMI levels, and the presence of concomitant diseases. Without this, even a validated device can lead to erroneous clinical decisions.

Despite the growing volume of data confirming the potential of wearable devices in cardiac monitoring, the process of their validation is fraught with a number of systemic difficulties that often remain beyond the scope of manufacturers' marketing statements. One of the most acute problems is the lack of representativeness of the studied populations. A 2022 meta-analysis showed that 78% of the validation studies were dominated by healthy volunteers under the age of 50 with a normal body mass index and no pronounced vascular or skin changes [8]. Meanwhile, elderly patients, people with obesity, dark skin pigmentation or peripheral arteriopathy constitute the main target group for monitoring arterial hypertension and arrhythmias. The reliability of the devices in these cohorts is often not verified, which makes extrapolating the results to real clinical practice extremely risky.

The problem of validation is particularly acute in the case of technologies that claim to measure blood pressure without using a cuff. Such solutions based on the analysis of the photoplethysmographic signal in combination with machine learning algorithms are actively being promoted to the consumer market. However, according to experts from the European Society of Hypertension, there is currently no generally accepted calibration standard for such systems. Most algorithms require "personal adjustment" – a single or periodic comparison with the readings of the tonometer – but this procedure is not standardized, and its frequency and conditions are at the discretion of the user [9]. As a result, even minor changes in the physiological state (for example, changes in vascular tone during colds) can lead to systematic errors that the user is unable to identify.

An additional layer of uncertainty is introduced by the so-called environmental and biological interferences.

The PPG signal, which underlies most smart watches, is extremely sensitive to movement: even when walking lightly, the signal-to-noise ratio deteriorates sharply, which leads to false alarms or, conversely, skipping episodes of arrhythmia [10]. The effect of skin pigmentation is equally significant: studies show that in individuals with a dark phototype (Fitzpatrick IV–VI), the amplitude of the PPG signal can be 30-50% lower, which reduces the reliability of measurements. In addition, factors such as low ambient temperature (causing vasoconstriction), swelling, tattoos in the area of wearing the device, and even the type of strap – all this creates a "background noise" that most algorithms are unable to filter correctly.

Taken together, these limitations create a situation in which the device can demonstrate high accuracy in the laboratory, but lose reliability in everyday life - exactly where its use is intended. Without mandatory stratification by demographic, anthropometric, and clinical characteristics, without standardization of calibration conditions, and without transparent accounting of artifacts, it is impossible to speak of genuine clinical validity.

The integration of wearable heart monitors into routine clinical practice is gradually transforming approaches to the detection of cardiovascular disorders, from reactive diagnosis based on symptoms to proactive screening of hidden pathologies. The most convincing evidence has been accumulated in the field of detection of paroxysmal atrial fibrillation (AF). This form of arrhythmia is often asymptomatic, especially in elderly patients, and may remain unrecognized for years, despite the high risk of thromboembolic complications [11]. The ARTESiA (Atrial Fibrillation and Risk of Stroke) study, published in The New England Journal of Medicine, demonstrated that even episodes of AF lasting more than 6 minutes per day are associated with a 30% increased risk of stroke compared with the absence of arrhythmia. In this context, devices with the ability to record a single-channel ECG (such as the Apple Watch or the KardiaMobile from AliveCor) show a significant advantage: in the mSToPS study, the frequency of AF diagnosis in the group using a wearable monitor exceeded the control 3.9 times over 12 months of follow-up [12].

Another important aspect is clarifying the diagnosis of hypertension. The classical measurement of blood pressure in a doctor's office can be misleading: some patients have an isolated increase in blood pressure in a clinical setting ("white coat" hypertension), while others have normal blood pressure in the office with a persistent increase in daily life (masked hypertension). The latter, according to a meta-analysis by Mancia et al., is associated with the same risk of cardiovascular events as persistent hypertension. Daily blood pressure monitoring (DBPM) remains the "gold standard" for differentiating these conditions, but its use is limited due to cost and lack of equipment. Wearable oscillometric tonometers such as the Omron HeartGuide, which have been validated using the ESH protocol, are increasingly being considered as an alternative. Although they do not replace DBPM, regular home measurements (as recommended by ESH 2023) can reliably detect masked hypertension, provided that the protocol is strictly followed: measurements at rest, at the same time, without talking or movement.

Digital technologies are particularly valuable when working with vulnerable categories of patients – the elderly and people with chronic heart failure (CHF). Elderly people have decreased sensitivity to the symptoms of arrhythmias; in patients with CHF, even small changes in heart rate or rhythm may precede decompensation. The possibility of remote monitoring makes it possible to detect deterioration at an early stage [13]. To structure the clinical scenarios, Table 2 presents the key areas of application, the level of evidence, and the main limitations.

Table 2

Clinical scenarios for the use of wearable heart monitors

The clinical challenge	Device type	Уровень доказательности	Main limitations
Screening of paroxysmal AF	Devices with single-channel ECG	I, A	It does not detect other types of arrhythmias.
Detection of masked hypertension	Wearable oscillometric tonometers	IIa, B	Requires adherence to the measurement protocol
Heart rate monitoring in CHF	PPG trackers + telemedicine platform	IIb, B	Reduced accuracy during physical activity
Differentiation of "white coat" hypertension	Home tonometers with in-app synchronization	I, A	Dependence on the regularity and correctness of measurements

Despite the rapid development of digital heart monitors, their clinical use is hampered by a number of fundamental technical and physiological limitations that often remain in the shadow of marketing promises. The most critical problem remains the unreliability of measuring blood pressure (BP) without using a pneumatic cuff. Most "frameless" solutions rely on analyzing the shape of the photoplethysmographic (PPG) signal in combination with machine learning algorithms [19]. However, as shown by a systematic

review published in Nature Medicine, none of the 28 tested applications and devices demonstrated accuracy that met the requirements of the ISO 81060-2 standard: the average error exceeded 8 mmHg, and the standard deviation was 12 mmHg, which makes such measurements clinically unacceptable. Moreover, most algorithms require personal calibration according to the "gold standard", but this procedure is not standardized, and the frequency of recalibration is not determined, which creates the risk of systematic bias when changing vascular tone (for example, with a cold or medication) [20].

The second important aspect is the limited sensitivity to rare or atypical arrhythmias. Modern devices, especially those based on PPG, are optimized for detecting atrial fibrillation, the most common form of paroxysmal arrhythmia. However, their ability to detect ventricular extrasystoles, paroxysmal tachycardia, or blockages is extremely low. In the WATCH-AF study conducted on a cohort of 300 patients with confirmed arrhythmias, the Apple Watch correctly identified AF in 97% of cases, but missed 89% of ventricular tachycardia and 76% of supraventricular tachycardia [2]. This creates a false sense of security: the patient, receiving a "normal" status from the device, may ignore alarming symptoms that require urgent diagnosis.

The widespread introduction of wearable heart monitors into everyday life poses a number of complex ethical and legal issues for society and the healthcare system that go far beyond technical accuracy. Personal data protection and confidentiality come first. Most consumer devices collect not only biometric data (heart rate, rhythm, sleep), but also geolocation, behavioral patterns, and in some cases even voice recordings. At the same time, many applications transfer this data to third parties (advertising networks, analytics companies) as part of "improving the user experience." In conditions where heart rate data can reveal a psychoemotional state or the presence of hidden diseases, this level of protection becomes unacceptable from an ethical point of view.

The second problem is the issue of legal liability for diagnostic errors. If a patient, trusting the smartwatch's notification of a "normal rhythm," postpones a visit to the doctor and suffers a stroke due to unrecognized atrial fibrillation, who is responsible: the algorithm developer, the device manufacturer, the app store, or the user himself? To date, the legal framework in most countries does not provide a clear answer. In the United States, the FDA explicitly states that manufacturers are responsible only if the device is classified as a medical device and has passed registration. However, many companies deliberately position their products as "wellness tools", avoiding regulatory control, but at the same time using formulations like "detecting signs of arrhythmia" – which creates a legal gray area. A similar situation is observed in the EU, despite the entry into force of the MDR (Medical Device Regulation).

This is directly related to the differences in regulatory classification between "medical" and "consumer" devices. In the United States, the FDA divides decisions by risk level: devices designed for diagnosis or treatment fall under Class II (require 510(k) notification), while activity trackers are not regulated as medical devices. In Europe, MDR has been in effect since 2021, which clearly classifies any software used to diagnose arrhythmias as Class IIa or higher, which requires clinical evaluation and post-marketing surveillance. In Russia, the situation is more complicated: according to the Order of the Ministry of Health No. 804n, devices that measure blood pressure or register an ECG are subject to mandatory registration with Roszdravnadzor as medical devices. However, in practice, many applications circumvent this requirement by claiming that they "do not measure, but only display data from an external sensor" – despite the fact that the sensor itself can be integrated into the same smartphone.

Thus, the legal landscape remains fragmented and often lags behind technological innovations. Without harmonizing regulatory requirements, clearly delineating responsibilities, and strengthening personal data protection, the mass adoption of wearable heart monitors may carry more risks than benefits, especially in vulnerable populations.

Despite the growing popularity of wearable heart monitors, their potential to improve outcomes in cardiovascular diseases remains inaccessible to a significant part of the population due to significant economic barriers. The most obvious of these is the high cost of devices, especially those that have passed clinical validation. For example, an Omron HeartGuide medical tonometer or an Apple Watch smartwatch with an ECG function cost between 35,000 and 60,000 rubles in Russia, which exceeds the average monthly pension of an elderly person with CVD. In the United States, a similar problem exists: according to a study published in the JAMA Network Open, only 28% of low-income patients (<200% of the federal poverty threshold) owned a device capable of monitoring heart rate, compared with 76% in the high-income group. This creates the so-called "digital divide in healthcare", in which the advantages of digital technologies go mainly to socially well-off strata, exacerbating existing inequalities in access to quality care [21].

The second, no less significant barrier is the lack of coverage from insurance and government systems. In most countries, including Russia, wearable devices are not included in the list of goods subject to compulsory medical insurance or voluntary medical insurance, even if they have proven clinical effectiveness. In the United States, Medicare and most commercial insurers only

cover traditional Holter monitors or DBPM, but not smartwatches or PPG trackers, despite data on their effectiveness in screening for AF. The situation varies in Europe: in Germany and France, individual digital therapeutic applications (DiGA) are included in the reinvention, but only if they undergo a rigorous assessment of their usefulness (for example, CardioMood for CHF). However, even in these countries, coverage of wearable devices (and not just software) remains the exception, not the rule.

This gap is especially dangerous in the context of stroke prevention in the elderly – it is the group that benefits most from early detection of AF, but is least able to afford modern technology. As the authors note in the WHO Digital Health Review, "without subsidy and government support mechanisms, digital innovation risks becoming a privilege rather than a tool for public health."

Thus, without a government policy aimed at subsidizing, including in the lists of reimbursement or creating preferential access programs for vulnerable groups, digital heart monitors will remain a tool not for reducing, but for reproducing social and medical inequality.

The future of digital cardiac monitoring lies beyond traditional PPG and ECG sensors. Non-contact methods for measuring hemodynamic parameters are one of the most promising areas. Research conducted at the Massachusetts Institute of Technology and the University of Texas demonstrates the possibility of recording heart rate and heart rate variability using radio frequency signals (for example, Wi-Fi or UWB) or computer vision through the analysis of micro–movements of the skin in a video stream from a conventional camera. Although such technologies are still at the stage of laboratory prototypes, their potential for monitoring elderly patients at home or during sleep is extremely high: measurement takes place passively, without the need to put on a device.

At the same time, there is a trend towards multimodal sensors capable of simultaneously monitoring not only heart rate and rhythm, but also physiological biomarkers – hydration level (through impedance), stress (by heart rate variability and galvanic skin response), even glucose (in experimental optical systems). For example, the BioIntelliSense BioSticker platform already integrates data on temperature, respiration, activity, and heart rate for early detection of decompensation in CHF [2]. This approach allows you to switch from "parameter monitoring" to "condition monitoring", which is fundamentally important for chronic diseases.

The key condition for the clinical applicability of these data remains their integration into electronic medical records (EMR). Without this, the information remains an "island" in the user's application. In the USA, the SMART on FHIR initiative, supported by ONC and major EHR platforms (Epic, Cerner), allows you to securely transfer data from wearable devices directly to the EMC [3]. In Russia, similar attempts are being made within the framework of the Unified Digital Healthcare Platform project, but so far without mandatory compatibility standards.

The next logical step is the transition from reactive monitoring to predictive cardiology. Modern machine learning algorithms, trained on data arrays from cohorts like the UK Biobank or the Apple Heart Study, are already able to predict the risk of atrial fibrillation, hospitalization for CHF, or even sudden cardiac death weeks and months before the event. For example, the DeepHeart model, based on neural networks, uses not only heart rate, but also data on sleep, activity, and geolocation to assess cardiovascular risk with AUC = 0.87.

However, the key challenge remains the individualization of algorithms. According to a Stanford study, "universal" models lose up to 40% accuracy when applied to ethnic or age groups not represented in the training sample. Therefore, the future belongs to adaptive AI systems that learn from the data of a particular patient over time, clarifying anxiety thresholds, taking into account his physiological characteristics and behavioral patterns.

Conclusions. Today, the landscape of mobile applications and wearable devices for monitoring blood pressure and heart rate is a complex mosaic of reliable, partially validated and frankly speculative solutions. Devices that have passed independent clinical verification according to international standards can be viewed with cautious confidence, such as oscillometric tonometers in the smartwatch format (Omron HeartGuide) or systems with the ability to register a single–channel ECG (Apple Watch, KardiaMobile). Their accuracy in compliance with the measurement protocol has been confirmed in numerous studies, and the data can be useful both for screening atrial fibrillation and for clarifying the diagnosis of "unclear" hypertension. At the same time, solutions claiming to measure blood pressure without a cuff or promising universal diagnosis of arrhythmias based on the PPG signal alone remain experimental and should not be used to make clinical decisions.

However, even the most precise technologies will not become part of medicine without interdisciplinary dialogue. Engineers should develop not just "smart" sensors, but tools that meet real clinical needs. Cardiologists should actively participate in validation and determine which data really affects outcomes. Regulators should ensure transparency of classification and protect patients from false statements. And patients should not be passive users, but informed participants in the process who understand both the capabilities and limitations of their devices.

The future of digital cardiac monitoring is promising, but its implementation requires not speeding up implementation at any cost, but a responsible, step-by-step and ethical approach. Further research is needed, focused not on demonstrating technological capabilities, but on assessing the real impact on health, safety and equity in healthcare. Only in this case, wearable technologies will be able to justify their potential – not as ordinary gadgets, but as tools to prolong and improve life.

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