

Research Article

# Opinion Paper: Smartwatches in Healthcare: Revolutionizing Health or Creating Data Confusion?

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## Abstract

Smartwatches have gained significant attention for their role in advancing digital health interventions and enhancing wellbeing. These modern technologies have the potential to revolutionize patient care by making healthcare more accessible and personalized. By promoting preventive care, shifting services from hospitals to communities, and transitioning from analog to digital healthcare systems, smartwatches can help individuals stay healthier and reduce hospital visits.

A key aspect of this transformation is the integration of smartwatch data into a unified patient record, ensuring comprehensive access to health information. However, with over 20 smartwatch manufacturers, offering multiple models with diverse health-monitoring capabilities, critical questions arise: What data is collected? How is it stored? Should any of it be integrated into medical records? Beyond the risks of data misuse for financial purposes, persistent challenges include ensuring accuracy, reliability, and standardization. A recent IFCC best practice publication on incorporating patient-generated health data into Electronic Health Records (EHRs) [1] highlights essential questions that must be addressed before smartwatch data can contribute meaningfully to healthcare. This paper explores these issues, weighing the potential benefits of smartwatches against the complexities of data integration and management.

## Introduction

Globally, more than 20 smartwatch manufacturers produce at least 29 models with health tracking capabilities. Basic models measure heart rate, oxygen levels, sleep patterns, step count, distance, and calories expenditure. More advanced versions can provide ECG (Electrocardiogram) readings, mental and physical well-being scores, menstrual health tracking, skin temperature variation, breathing rate, body composition metrics, blood pressure monitoring, and blood glucose tracking. Despite these innovations, significant variations exist even within the same manufacturer's line-up.

For instance, Apple Watches rely on photoplethysmography (PPG) for heart rate variability (HRV) tracking, whereas Samsung Watches also employ ECG sensors. Such disparities highlight the broader issue of limited standardization, particularly for PPG-based devices, which dominates the market but often face accuracy challenges during physical activity. However, automated biosensor detection of unwitnessed cardiac arrest, followed by immediate dispatch of medical assistance, could greatly improve survival rates, underscoring the importance of reliable, standardized measurements. Although some devices achieve continuous monitoring during sleep, consistency remains a challenge [2], these challenges among others are explored in detail by Li et al [3].

User-entered demographic data-used to calibrate step distance and calorie counts can introduce inaccuracies, as can the step-tracking feature which relies on a mix of location data and watch movement. In some cases, users can inflate their step counts simply by shaking the watch without actually walking. By moving your watch arm up and down around 6 inches and going from left to right (or vice versa) across the width of your body the Fitbit sense will count steps for as long as the movement keeps going. Despite these limitations, smartwatches provide tangible personal benefits: daily activity goals, heart rate monitoring, and sleep analysis can all foster healthier habits and an increased sense of well-being. A recent review including 35 studies and other publications pointed out that smartwatches can serve as valuable tools for monitoring health by increased acceptance, but they should not be solely relied upon for diagnosing illnesses in most instances. According to the editors, one problem is that smartwatches focus on aggregating biomedical data and do not take a holistic view of the patient, and the over-reliance on smartwatches and the fewer face-to-face doctor visits lead to a violation of the principle of non-maleficence [4].

Device choice is frequently tied to user smartphone ecosystems. Apple Watches work only with iPhones, while Fitbit and Garmin devices support both iOS and Android. More budget-friendly options are often tied to a single phone brand or Android-based systems.

Although some standardization exists through licensing agreements among manufacturers. The overall variability

in hardware and software poses a hurdle for integrating smartwatch data into clinical or population-wide health studies. Nevertheless, as data accuracy and interoperability continue to improve, smartwatches hold significant potential for supporting evidence-based health interventions and personalized wellness strategies.

## Methods

Below is an assessment of the listed data and trends regarding smartwatch health functionalities (Table 1-4). Since these figures come from a specific (and somewhat future-dated) source (July 2024 internet search), it's not possible to verify them against publicly available references at this time. The initial data searches were carried out to create a spreadsheet of smartwatch capabilities within the healthcare arena. The search engines used were google.com and bing.com. Both search engines were used to ensure that the maximum number of smart watches were discovered. The initial search terms used were 'what smart watches are available globally' from this a list of watches was collated. For each watch manufacturer the question was then asked, "Huawei smart watch for health monitoring" (Huawei used as an example. These produced smartwatch versions that were advertised for their health monitoring features. Then for each watch manufacturer up to 3 of the latest versions were chosen to get detailed information and the search term "Huawei smart watch 4 technical specifications" was entered and the spreadsheet updated from the manufacturers technical specifications. Given the rapid expansion of smartwatch manufacturers and the frequent release of new models with diverse features, any list of currently available devices is likely to become outdated by the time the article reaches publication. Nonetheless, the underlying rationale and insights presented in this paper remain relevant and enduring.

However, from a purely logical and industry-knowledge standpoint, the numbers and features mentioned appear internally consistent and align reasonably well with known smartwatch capabilities. Here are some points to consider: 29 of 30 models included heart rate sensors, while only 13 offered ECG monitoring.

- **Heart Rate Sensors (29 of 30 models):** It is very common for modern smartwatches to include optical heart rate sensors. Having 97% coverage is highly plausible
- **Blood Oxygen Monitoring (20 of 30 models):** SpO<sub>2</sub> sensors have become more prevalent, especially after 2020, but only 2 included blood pressure monitoring
- **Blood Glucose Logging (6 of 30 models):** Actual non-invasive glucose measurement is still in development, so most likely these devices support manual logging or integration with third-party sensors.
- **ECG Monitoring (13 of 30 models):** ECG functionality requires more advanced hardware and regulatory approvals, so fewer models offer it

- **Sleep Monitors (25 models) and Activity Tracking (26 models):** These features are fairly standard.
- **Distinct Health-related metrics (28 in total):** It's very plausible that across 30 models, manufacturers advertise nearly 30 distinct metrics (e.g., steps, calories, VO<sub>2</sub> max, HRV, stress scores, etc.). The statement that no single metric is universally available across all models underscores the lack of industry-wide standardization.
- **Some models included unique features**
  - **Garmin Venu 3:** Known to have advanced health reports and nap detection, (provides a comprehensive overview of sleep quality, including sleep stages, stress levels, heart rate variability (HRV), and recovery status, while its “nap detection” feature automatically tracks and logs naps, allowing the user to see how they impact overall sleep quality and providing insights on ideal nap duration and timing) which aligns with Garmin's emphasis on detailed fitness and wellness data.

- **ASUS HC A05:** While less well-known, the mention of pulse transit time measurement (this is a measure of blood flow speed, which can indicate emotional stress and overall health) is consistent with ongoing industry experiments to refine blood pressure or stress estimates.

This overview of the smartwatch market, based on direct manufacturer specifications, provides a snapshot of market trends and illustrates the wide range of features and health indicators offered by different brands, reflecting the state of smartwatch technology projected through July 2024. The diversity of metrics and features presents a well-known challenge for integrating smartwatch data into clinical or population health research. The variability of measurement methods and the lack of standardized health metrics further complicate harmonization efforts.

**Table 1:** Health Functions of 10 Available Smart Watches (1).

Functionality	Apple watch v9.0	Apple watch ultra	Apple watch SE	Fitbit sense 2	Fitbit Charge 4	Fitbit Versa 4	Fitbit inspire 3	Google pixel watch	Google Pixel watch 2	Samsung galaxy watch 4
Blood oxygen measurement, the percentage of blood saturated with oxygen	Blood Oxygen App	Blood Oxygen App		SpO2 (blood oxygen) tracking + breathing rate	SpO2 (blood oxygen) tracking + breathing rate	SpO2 (blood oxygen) tracking + breathing rate	SpO2 (blood oxygen) tracking + breathing rate	SpO2 (blood oxygen) tracking + breathing rate	SpO2 (blood oxygen) tracking + breathing rate	Bioactive sensor measures SP02 in real time
ECG (Electrocardiogram) measures the electrical activity of the heart	ECG App	ECG App		ECG App	ECG App	ECG App		ECG App	ECG App	ECG in real time
Heart rate notifications alert the user if the heart rate deviates from a predetermined level	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	High and low heart rate notifications	Electrical and optical heart rate sensor
Estimated blood pressure by monitoring blood flow changes										
Sleep monitor measures sleep duration, quality and sleep stages.	Sleep stages	Sleep stages	Sleep stages	Sleep stages, sleep profile, sleep score + smart wake alarm	Sleep stages, sleep profile, sleep score + smart wake alarm	Sleep stages, sleep profile, sleep score + smart wake alarm	Sleep stages, sleep profile, sleep score + smart wake alarm	Sleep stages, sleep profile, sleep score	Sleep stages, sleep profile, sleep score	Sleep monitor, holistic analysis, sleep coaching
Health Mental well being provides insights into individual health and mental state	Mental well being	Mental well being	Mental well being	Wellness report	Wellness report	Wellness report	Wellness report	Wellness report	Wellness report	
Menstrual cycle tracking logs dates and symptoms to predict future periods.	Cycle tracking	Cycle tracking	Cycle tracking	Menstrual health tracking	Menstrual health tracking	Menstrual health tracking	Menstrual health tracking	Menstrual health tracking	Menstrual health tracking	
Skin temperature is used for insights like sleep monitoring.	Temperature sensor	Temperature sensor		Skin temperature variation	Skin temperature variation	Skin temperature variation	Skin temperature variation		Skin temperature variation	
Stress App, Reflections, Daily Readiness and Medical Information				EDA scan app for stress management & reflections & daily readiness score	EDA scan app for stress management & reflections & daily readiness score	EDA scan app for stress management & reflections & daily readiness score	EDA scan app for stress management & reflections & daily readiness score	EDA scan app for stress management & reflections & daily readiness score	EDA scan app for stress management & reflections & daily readiness score	

Activity tracking monitors and records various physical activity throughout the day	Activity tracking	Activity tracking	Activity tracking	Active zone minutes	Active zone minutes	Active zone minutes	Active zone minutes	Active zone minutes	Active zone minutes	Activity tracking
Steps, distance and calories				Steps, distance and calories + floor climbed	Steps, distance and calories	Steps, distance and calories + floor climbed	Steps, distance and calories	Steps, distance and calories + floor climbed	Steps, distance and calories + floor climbed	
Exercise modes monitor specific types of physical activity e.g. cycling				Exercise modes with smart track auto recognition & workouts	Exercise modes with smart track auto recognition & workouts	Exercise modes with smart track auto recognition & workouts	Exercise modes with smart track auto recognition & workouts	Exercise modes with smart track auto recognition & workouts & pace training	Exercise modes with smart track auto recognition & workouts & pace training	
Blood glucose tracking is currently made by entering glucose levels in an App				Glucose tracking (App)	Glucose tracking (App)	Glucose tracking (App)	Glucose tracking (App)	Glucose tracking (App)	Glucose tracking (App)	

**Table 2:** Health Functions of 10 Available Smart Watches (2).

Functionality	Samsung Galaxy 5	Samsung Galaxy 6	One Plus watch 2	CMF watch Pro	Garmin Venu 3	Huawei watch ultimate	Huawei watch 4	ASUS smart watch HC A05	Acer Leap ware	HTC Grip
<b>Blood oxygen measurement, the percentage of blood saturated with oxygen</b>	SpO2 (blood oxygen) tracking +VO2 Max	SpO2 (blood oxygen) tracking +VO2 Max	blood oxygen monitoring single point or all day	blood oxygen monitor + breathing training	Pulse oxygen sensor + VO2 Max + breathing rate			Pulse oxygen sensor		
<b>ECG (Electrocardiogram) measures the electrical activity of the heart</b>	ECG App	ECG App					ECG sensor	ECG sensor		
<b>Heart rate notifications alert the user if the heart rate deviates from a predetermined level</b>	Electrical and optical heart rate sensor	Electrical and optical heart rate sensor	High/low heart rate warning.	Heart rate alert	Heart rate variability notifications	Optical heart rate sensor	Optical heart rate sensor	Aerobic heart rate sensor	Heart rate sensor	
<b>Estimated blood pressure by monitoring blood flow changes</b>	Blood pressure monitoring	Blood pressure monitoring								
<b>Sleep monitor measures sleep duration, quality and sleep stages.</b>	Sleep stages	Sleep stages	Sleep monitor - Sleep stages	Sleep monitor	Sleep monitoring + nap detection+ jet lag adviser			Sleep monitoring	Sleep monitoring	Sleep monitoring
<b>Health Mental well being provides insights into individual health and mental state</b>										
<b>Menstrual cycle tracking logs dates and symptoms to predict future periods.</b>					Menstrual health tracking					
<b>Skin temperature is used for insights like sleep monitoring.</b>	Infrared Temperature Sensor	Infrared Temperature Sensor			Skin temperature variation	Temperature sensor	Temperature sensor			
<b>Stress App, Reflections, Daily Readiness and Medical Information</b>	Stress level management, Body fat, skeletal muscle & body water %,	Stress level management, Body fat, skeletal muscle & body water %,	Stress monitoring	Stress monitoring	Stress tracking + Meditation & Health Report			Stress tracking		
<b>Activity tracking monitors and records various physical activity throughout the day</b>	Activity tracking	Activity tracking	Activity tracking	Activity tracking	Activity tracking			Activity tracking	Activity tracking	Activity tracking

Steps, distance and calories			Steps, distance and calories		Steps, distance and calories + floors climbed			Steps, distance and calories + floors climbed	Steps and pace	Distance and calories
Exercise modes monitor specific types of physical activity e.g. cycling			100+ sports modes with 6 types of auto recognition	100+ sports modes					Multi sport mode	
Blood glucose tracking is currently made by entering glucose levels in an App										

**Table 3:** Health Functions of 10 Available Smart Watches (3).

Functionality	Honor watch GS3	LG Smartwatch W110	HD Smart Fitness Watch	Motorola Moto 100 smart watch	NOKIA Steel HR	Oppo Smart watch	Real Me Watch S	Withings scan watch 2	Xiaomi Mi Watch S2	ZTE Watch
Blood oxygen measurement, the percentage of blood saturated with oxygen	Blood Oxygen Monitor 24/7 tracks blood oxygen.			SpO2 monitor			SpO2 sensor	SpO2 sensor + respiratory rate	SpO2 sensor	SpO2 sensor
ECG (Electrocardiogram) measures the electrical activity of the heart								ECG		
Heart rate notifications alert the user if the heart rate deviates from a predetermined level	8 Channel PPG Heart Rate Sensor.	PPG (Heart rate monitor)	Heart rate sensor	HRM	Heart rate infrared PPG sensor	Heart rate sensor	Heart rate sensor	Heart rate sensor	Heart rate sensor	Heart rate sensor
Estimated blood pressure by monitoring blood flow changes										
Sleep monitor measures sleep duration, quality and sleep stages.	Sleep tracking		Sleep monitor		Time it takes to fall asleep, sleep cycles	Sleep monitor	Sleep monitor	sleep monitor		Sleep monitor
Health Mental well being provides insights into individual health and mental state										
Menstrual cycle tracking logs dates and symptoms to predict future periods.								Menstrual cycle tracking		
Skin temperature is used for insights like sleep monitoring.								Body temperature sensor	Body temperature sensor	
Stress App, Reflections, Daily Readiness and Medical Information							Meditation		BMI composition	
Activity tracking monitors and records various physical activity throughout the day	Activity tracking		Activity tracking	Activity tracking	Activity tracking	Activity tracking	Activity tracking	Activity tracking		Activity tracking
Steps, distance and calories					Steps, distance and calories		Steps, distance and calories	Steps distance		Steps, distance and calories
Exercise modes monitor specific types of physical activity e.g. cycling	>100 sport modes			26 sports modes	Running and swimming	Runs, swims, bike rides, walks +	16 sport modes	>10 modes		12 sports modes
Blood glucose tracking is currently made by entering glucose levels in an App										

## Results and Discussion

Smartwatches track movement, exercise bands assess users' sleep habits, and flexible bandages monitor body temperature, heart rate, and fluid levels. These devices provide real-time data from integrated sensors and analyze the information gathered. Consumers can use their smartphones or other mobile apps to track their health using data from wearable devices [5]. To achieve clinical utility, smartwatches must measure validated, accurate, and actionable health parameters. Although most consumer-grade devices do not meet medical-grade standards, certain sensors have demonstrated promise in clinical monitoring, early disease detection, and chronic disease management. Standardizing key health metrics across devices could improve their integration into clinical workflows and enhance evidence-based decision-making. The following section outlines what health care data is collected; it is normally synchronized with the users smartphone on an application that is proprietary to the Smartwatch manufacturer which may also be the same for the phone e.g. Apple. The integration into medical records would need to follow the considerations outlined in 3.2.

### Key Health-Tracking Features Requiring Standardization

1. **Heart Rate Monitoring (HR):** Detects trends in resting heart rate, stress, infections, and arrhythmias. While optical PPG sensors are reliable for resting HR, they are less accurate during intense activity.
  2. **Electrocardiogram (ECG/EKG):** Identifies atrial fibrillation and other arrhythmias. FDA-cleared models (e.g., Apple Watch, Samsung Galaxy Watch) provide single-lead ECGs but cannot replace full 12-lead ECGs.
  3. **Blood Oxygen Saturation (SpO2):** Useful for sleep apnoea screening and respiratory conditions. While less accurate than medical pulse oximeters, they can aid trend analysis.
  4. **Heart Rate Variability (HRV):** Reflects autonomic nervous system balance. Low HRV correlates with cardiovascular risk, stress, and chronic fatigue.
  5. **Blood Pressure Monitoring:** Emerging technology, currently requiring external calibration. Most wearables lack FDA clearance.
  6. **Sleep Tracking:** Detects sleep duration, disruptions, and stages, aiding in identifying insomnia and apnoea.
  7. **Skin Temperature Trends:** Tracks menstrual cycles and early signs of infection. Relative changes, rather than absolute values, are more informative.
  8. **Activity and Step Tracking:** Supports exercise adherence and rehabilitation.
  9. **Continuous Glucose Monitoring (CGM)**
- Integration:** Emerging partnerships (e.g., Apple Watch with the Dexcom G7 system able to display glucose data directly on compatible Apple Watch model. s. At present, no smartwatch on the market is capable of measuring blood glucose independently. The partnership between Apple and Dexcom-is

cited to illustrate the level of regulatory rigor and technological performance that a consumer-grade smartwatch would need to meet before being acceptable for healthcare use.

**10. Fall Detection and Emergency Alerts:** Crucial for elderly users or those with mobility issues, automatically alerting emergency contacts when needed.

### Clinical Integration Considerations

• **Regulatory approval** (e.g., US Food and Drug Administration (FDA) clearance) and validation through peer-reviewed studies, the paper by Li et al describes the basis for designing a study to evaluate the heart rate variability measurements across smart watches [3]. There are multiple regulatory agencies globally and the term FDA is used in this paper to represent regulatory oversight. Dependent on the country where the healthcare data is collected and used would determine which regulatory body would give approval. This adds extra time and costs for commercial smart watch manufacturers if they want to sell their watches for healthcare purposes in multiple regulatory jurisdictions. The following challenges need to be addressed for manufacturers to achieve FDA or other regulatory approval, ensuring that smartwatch health features are both safe and effective for consumer use:

- **Accuracy and Reliability:** Smartwatches must provide precise and consistent health measurements. For instance, the FDA has cautioned against using smartwatches or smart rings for measuring blood glucose levels due to concerns about accuracy, emphasizing the potential risks of relying on unauthorized devices for critical health decisions [6].
- **Regulatory Compliance:** Manufacturers must adhere to FDA guidelines, which can be complex and time-consuming. The FDA has initiated pilot programs to streamline the approval process for digital health technologies, aiming to balance innovation with patient safety [7].
- **Post-Market Surveillance:** Continuous monitoring of device performance after-market release is essential. The FDA conducts post-market evaluations to assess how wearable devices influence medical care and patient outcomes, ensuring ongoing compliance and effectiveness [8].
- **Data Privacy and Security:** Protecting user data is crucial. Wearable devices collect sensitive health information, necessitating robust security measures to prevent unauthorized access and ensure compliance with privacy regulations [9].
- **Data standardization for interoperability with EHRs:**

By focusing on the following areas, the healthcare industry can move towards seamless integration of smartwatch-generated health data into EHRs, enhancing patient care and facilitating comprehensive health monitoring:

- **Adopt Established Interoperability Standards:** Implementing guidelines like the ITU interoperability guidelines for FHIR ensures that personal health devices and systems can communicate effectively. These guidelines



promote interoperability, security, and ease of use by building on existing industry standards such as Bluetooth and ISO/IEEE 11073 [10].

- **Implement Standardized Data Formats:** Utilizing uniform data formats and terminologies, such as those recommended by the American Nurses Association (ANA), facilitates consistent data capture and representation across different systems. This standardization supports accurate documentation and reporting of health information [11].
- **Ensure Secure Data Sharing Protocols:** Developing secure methods for data transmission and storage is crucial. Ensuring that health data is shared in compliance with privacy regulations protects patient information and maintains trust in digital health technologies [12].
- **Enhance EHR System Interoperability:** Improving the interoperability of EHR systems themselves is essential. Addressing issues related to poor system interoperability can lead to better quality of care and patient safety [13].
- **Educate Healthcare Providers:** Training healthcare professionals on the effective use of smartwatch data ensures that they can interpret and integrate this information into clinical decision-making processes, maximizing the potential benefits of wearable health technology [8].
- Secure, user-controlled data sharing.
- Minimizing false alarms that may cause unnecessary anxiety.
- Ensuring inclusivity in algorithm training to avoid biases.

If the challenges associated with glucose monitoring [6] are taken as an example, the following would need to be met:

1. **Accuracy and Precision:** Non-invasive glucose monitoring methods, such as those potentially used in smartwatches, face difficulties in achieving the accuracy required for medical decision-making. Inaccurate readings could lead to inappropriate treatment adjustments, posing risks to patient health.
2. **Technological Limitations:** Current sensor technologies may struggle to accurately detect glucose levels without invasive methods. Factors like skin thickness, temperature, and hydration can affect sensor readings, leading to variability and potential inaccuracies.
3. **Regulatory Compliance:** Devices intended for medical use must undergo rigorous evaluation to demonstrate safety and effectiveness. The FDA classifies continuous glucose monitoring (CGM) systems as Class II devices, requiring special controls and premarket notification.
4. **Clinical-Grade Specifications Required:**
  - **Analytical Accuracy:** Devices should meet specific accuracy thresholds, such as those outlined in the FDA's recognized consensus standards for glucose monitoring systems.
  - **Precision:** Consistent performance across multiple

measurements is essential to ensure reliability in monitoring and treatment decisions.

- **Detection of Critical Values:** The ability to accurately identify hypoglycaemic and hyperglycaemic events is crucial for timely interventions and patient safety.
- **Trend Analysis:** Providing accurate trends and patterns in glucose levels can aid in long-term diabetes management and therapy adjustments.

#### Chronic Condition Use Cases

- **Diabetes:** With 38 million Americans diagnosed and 98 million with prediabetes [14], CGM integration and activity tracking are valuable for disease management. In 2022, diabetes-related costs reached \$413 billion [15].
- **Hypertension:** Smartwatch blood pressure monitoring could aid management if validated.
- **Heart Disease:** More than 944,800 annual U.S. deaths result from heart disease and stroke [16]. ECG, HR, and HRV tracking could support early detection and intervention. Cardiovascular disease costs are projected to reach \$2 trillion by 2050 [17]. These diseases take an economic toll, as well, costing the US health care system \$254 billion per year and causing \$168 billion in lost productivity on the job [18].

Beyond technological advancements, adequate user education is essential for maximizing the clinical utility of consumer smartwatches and other wearables. Integrating intuitive “poka-yoke” (error-proofing) design directly into apps can promote correct device usage and enhance patient adherence. There is a major question around digital literacy, a 2024 good things foundation report detailed that 1.6 million people in the UK don't have a smartphone, tablet or PC. Of a population of 84 million, 30% are unaware of local access points for device access or internet connection, 77% of those with no basic skills are over 65. This is a major consideration for the use of smart watches in healthcare as a major target for their value is keeping elderly people out of hospital whilst being able to monitor their wellbeing. If the digital literacy is poor in the UK, then the challenges for lower economic countries may provide significant challenges. [19]. Battery life remains a critical factor, as longer-lasting devices - such as the Withings ScanWatch 2 with its 30-day battery life - facilitate continuous data collection, reducing data gaps in long-term monitoring. Anecdotally most smart watches have a battery life after a full charge of between 18 hours and 7 days with the time being aligned with the number of associated apps and features that are used; most watches can be connected to your phone to read text messages and take calls, watches can also have wallet features turned on and dependent on frequency of usage of these features then battery life can be affected. If watches can become a clinical tool, then the need for continuous collection of data or the ability to record when charging is taking place becomes important.

Despite their promise, consumer wearables are not yet

diagnostic tools and should serve as adjuncts to, rather than replacements for, clinical assessments. Refining algorithms to minimize false positives is crucial to avoid unnecessary anxiety and clinical burden. Determining what constitutes a false positive or false alarm in wearable health monitoring raises important ethical considerations. An algorithm must be robust enough to flag clinically significant events without being so permissive that it generates frequent false alarms - or so restrictive that it misses true positives. While the scientific community sometimes employs “grey zones” to account for uncertainty near decision thresholds, such ambiguity can be difficult for users to interpret clearly.

Moreover, responsibility for interpreting results must be clearly defined. If the user is responsible, the device must convey clear guidance on what actions to take. If interpretation rests with the healthcare provider, systems must allow for seamless digital monitoring and alerting-ideally integrated with clinical data and workflows - for providers to respond appropriately. [20,21]. By enabling early detection of health anomalies, smartwatches could enhance preventive care, potentially reducing disease burden and healthcare costs. The integration of AI-driven avatars and cloud-based data collection further expands the impact of wearable technology. Virtual health assistants powered by AI can provide real-time feedback, behavioral coaching, and personalized health recommendations. Meanwhile, cloud platforms facilitate seamless data aggregation, remote monitoring, and AI-powered analytics, enabling healthcare providers to make more informed clinical decisions [22]. While unlimited access to digital

health information can inspire healthier behaviors in some individuals, excessive data monitoring may inadvertently lead to pathological symptom tracking and impaired functioning in others. For instance, continuous cardiac monitoring via commercially available smartwatches has been linked to new-onset health anxiety in certain patients. This highlights the need to balance the benefits of digital health technologies with potential psychological harm, especially in vulnerable populations [23]. Additionally, manufacturers must prioritize the inclusion of diverse populations in training datasets to ensure equitable performance across different demographics, ultimately improving patient outcomes. Understanding how different populations, such as young adults, older adults, and individuals with chronic conditions, interact with this technology is essential to optimize its impact. Researchers have developed and studied frameworks based upon smartwatches such as ROAMM (Real-time online assessment and mobility monitoring) in which the health applications present in the smartwatches are used to collect and preprocess data and dedicated servers are utilized to store and recover data and perform remote monitoring [24].

A significant barrier to integrating smartwatch data into healthcare systems lies in data ownership [25]. When users synchronize their watch with a mobile app, they digitally consent to the manufacturer’s ownership of that data. For healthcare providers to access this information, a formal agreement with the smartwatch manufacturer is required - ensuring that data-sharing adheres to privacy policies, user consent, and any applicable regulations.

**Table 4:** Potential Health Monitoring Functions of Smart Watches.

	<b>Heart Rate function</b>	<b>Blood Oxygen Monitoring</b>	<b>ECG</b>	<b>Activity monitoring</b>	<b>Sleep monitoring</b>	<b>Glucose Monitoring (App)</b>
<b>Apple watch v9.0</b>	x	x	x	x	x	x
<b>Apple watch ultra</b>	x	x	x	x	x	x
<b>Apple watch SE</b>	x			x	x	
<b>Fitbit sense 2</b>	x	x	x	x	x	x
<b>Fitbit Charge 4</b>	x	x	x	x	x	x
<b>Fitbit Versa 4</b>	x	x	x	x	x	x
<b>Fitbit inspire 3</b>	x	x		x	x	
<b>Google pixel watch</b>	x	x	x	x	x	x
<b>Google Pixel watch 2</b>	x	x	x	x	x	x
<b>Samsung galaxy watch 4</b>	x	x	x	x	x	x
<b>Samsung Galaxy 5</b>	x	x	x	x	x	x
<b>Samsung Galaxy 6</b>	x	x	x	x	x	x
<b>One Plus watch 2</b>	x	x		x	x	
<b>CMF watch Pro</b>	x	x		x	x	
<b>Garmin Venu 3</b>	x	x		x	x	
<b>Huawei watch ultimate</b>	x					
<b>Huawei watch 4</b>	x		x			x



ASUS smart watch HC A05	x	x	x	x	x	x
Acer Leap ware	x			x	x	
HTC Grip				x	x	
Honor watch GS3	x	x		x	x	
LG Smartwatch W110	x					
HD Smart Fitness Watch	x			x	x	
Motorola Moto 100 smart watch	x	x		x	x	
NOKIA Steel HR	x			x	x	
Oppo Smart watch	x			x	x	
Real me watch S	x	x		x	x	
Withings scan watch 2	x	x	x	x	x	x
Xiaomi Mi watch S2	x	x				
ZTE watch	x	x		x	x	

### Conclusion

The integration of smartphones and smartwatches into healthcare has transformed the way health data is transmitted, monitored, and acted upon, enabling more effective real-time communication between patients, participants, and healthcare providers. The flexibility of bidirectional, real-time control within healthcare applications offers a dynamic interface that adapts to individuals' evolving needs and environments. Smartwatches, with their discreet and continuous monitoring capabilities, have the potential to shift healthcare delivery from traditional clinical settings to the rhythm of patients' daily lives. This decentralization empowers individuals to take an active role in managing their health, increasing awareness, and encouraging healthier lifestyles. As such, wearable technology plays a pivotal role in enhancing patient engagement and fostering a culture of prevention.

Maximizing these benefits requires active collaboration among diverse stakeholders, including IVD companies, medical device manufacturers, healthcare practitioners, researchers, patients, and caregivers. Understanding how different populations, such as young adults, older adults, and individuals with chronic conditions, interact with this technology is key to tailoring its applications for maximum impact. Notable frameworks, such as ROAMM (Real-time Online Assessment and Mobility Monitoring), illustrate how smartwatch-based applications can collect, preprocess, and securely store health data for remote monitoring.

To fully realize the promise of smartwatches in medicine, critical challenges must be addressed: standardization, validation, data security, and regulatory compliance.

Overcoming these barriers will allow smartwatches to progress from consumer fitness tools to indispensable instruments of personalized, preventive, and patient-centered care, integrated seamlessly into the future of modern medicine.

### Declaration of Conflict of Interests

No authors work for or have any financial interests with any smart watch vendor, no funding was requested or received by any author.

### Ethical Approval

Ethical approval was not required for this research; all data is openly available on the internet.

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### Authors Contribution

All authors had opportunity to provide diverse commentary to the published work and were equal contributors.

### References

- Nichols JH, Assad RS, Becker J, Dabla PK, Gammie AJ, et al. Integrating Patient-Generated Health Data from Mobile Devices into Electronic Health Records Best Practice Recommendations by the IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM). *eJIFCC2024Vol35No4pp324-328* (accessed: 18/02/2025).
- Alnasser S, Alkalthem D, Alenazi S, Alsowinea M, Alanazi N, Al Fagih A. The Reliability of the Apple Watch's Electrocardiogram. *Cureus*. 2023;15(12):e49786. doi: 10.7759/cureus.49786. PMID: 38161560; PMCID: PMC10757793. (accessed: 18/02/2025).
- Li, K.; Cardoso, C.; Moctezuma-Ramirez, A.; Elgalad, A.; Perin, E. Heart Rate Variability Measurement through a Smart Wearable Device: Another Breakthrough for Personal Health Monitoring? *Int. J. Environ. Res. Public Health* 2023, 20, 7146. (accessed: 18/02/2025).
- Hosseini MM, Hosseini ST, Qayumi K, Hosseinzadeh

- S, Tabar SSS. Smartwatches in healthcare medicine: assistance and monitoring; a scoping review. *BMC Medical Informatics and Decision Making* (2023) 23:248. <https://doi.org/10.1186/s12911-023-02350-w> (accessed: 18/02/2025).
5. Chandel RS, Sharma S, Kaur S, Singh S, Kumar R, Smart watches: A review of evolution in bio-medical sector, *Materials Today: Proceedings*, Volume 50, Part 5, 2022, Pages 1053-1066, ISSN 2214-7853, <https://doi.org/10.1016/j.matpr.2021.07.460>. (accessed: 18/02/2025).
6. Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication | FDA Date issued Feb 21, 2024 (accessed: 18/02/2025).
7. Sumrai H., How FDA approvals affect your wearables, and how it is going to change. <https://www.wearable.com/wearable-tech/fda-wearables-state-of-play-239/> Jan 17, 2018 (accessed: 18/02/2025).
8. Post-Market Evaluation of Smartwatch Cardiovascular Notifications. FDA. <https://www.fda.gov/science-research/advancing-regulatory-science/post-market-evaluation-smartwatch-cardiovascular-notifications> September 2021 updated May 17, 2024 (accessed: 18/02/2025).
9. Goodings, A.J., Fadahunsi, K.P., Tarn, D.M., Henn, P., Shiely, F. and O'Donoghue, J., 2024. Factors influencing smartwatch use and comfort with health data sharing: a sequential mixed-method study protocol. *BMJ open*, 14(5), p.e081228. <https://doi.org/10.1136/bmjopen-2023-081228> (accessed: 18/02/2025).
10. ITU\_interoperability\_Design\_Guidelines\_for\_FHIR (accessed: 18/02/2025).
11. Standardization and Interoperability of Health Information Technology. ANA Position Statement. <https://www.nursingworld.org/practice-policy/nursing-excellence/official-position-statements/id/standardization-and-interoperability-of-health-information-technology>. June 11, 2014 (accessed: 18/02/2025).
12. Köhler C, Bartschke A, Fürstenau D, Schaaf T, Salgado-Baez E. The Value of Smartwatches in the Health Care Sector for Monitoring, Nudging, and Predicting: Viewpoint on 25 Years of Research. *J Med Internet Res*. 2024 25;26:e58936. doi: 10.2196/58936. PMID: 39356287; PMCID: PMC11549588. (accessed: 18/02/2025).
13. Li E, Clarke J, Ashrafi H, Darzi A, Neves AL. The Impact of Electronic Health Record Interoperability on Safety and Quality of Care in High-Income Countries: Systematic Review. *J Med Internet Res*. 2022;24(9):e38144. doi: 10.2196/38144. PMID: 36107486; PMCID: PMC9523524. (accessed: 18/02/2025).
14. Centers for Disease Control and Prevention. Diabetes Statistics Report. U.S. Dept of Health and Human Services; 2023. <https://www.cdc.gov/diabetes/php/data-research/index.html> (accessed: 18/02/2025).
15. Parker ED, Lin J, Mahoney T, et al. Economic costs of diabetes in the U.S. in 2022. *Diabetes Care*. 2023. doi: 10.2337/dci23-0085 (accessed: 18/02/2025).
16. Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 2018-2022 on CDC WONDER Online Database website. Reviewed April 26, 2024. Access May 3, 2024. <http://wonder.cdc.gov/mcd.html>. (accessed: 18/02/2025).
17. Tsao CW, Aday AW, Almarzooq ZI, Anderson CAM, et al.; American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2023 Update: A Report From the American Heart Association. *Circulation*. 2023;147(8):e93-e621. doi: 10.1161/CIR.0000000000001123. Epub 2023 Jan 25. Erratum in: *Circulation*. 2023;147(8):e622. doi: 10.1161/CIR.0000000000001137. Erratum in: *Circulation*. 2023;148(4):e4. doi: 10.1161/CIR.0000000000001167. PMID: 36695182. (accessed: 18/02/2025).
18. Kazi D, Elkind M, Deutsch A, Dowd W, et al. Forecasting the economic burden of cardiovascular disease and stroke in the United States through 2050: a presidential advisory from the American Heart Association. *Circulation*. 2024;149:e00–e00. doi: 10.1161/CIR.0000000000001258) (accessed: 18/02/2025).
19. Our Digital Nation. [www.goodthingsfoundation.org/policy-and-research/research-and-evidence/research-2024/digital-nation](http://www.goodthingsfoundation.org/policy-and-research/research-and-evidence/research-2024/digital-nation) (accessed:08/08/25)
20. Wearable Medical Devices: A Rational Guide for Activists and Regulators. *Wearable Medical Devices: A Rational Guide for Activists and Regulators - Science, Public Health Policy and the Law*. (accessed:07/08/25)
21. Ethics of digital health tools. [www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-18/ethics-of-digital-health-tools](http://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-18/ethics-of-digital-health-tools). (accessed:07/08/25)
22. AI Could Be the Key to Making the Smartwatches We Already Own Better. <https://www.cnet.com/tech/mobile/ai-could-be-the-key-to-making-the-smartwatches-we-already-own-better/>.( accessed:10/08/25)
23. Rosman L, Gehi A, Lampert R. When smartwatches contribute to health anxiety in patients with atrial fibrillation. *Cardiovasc Digit Health J*. 2020 (1):9-10. doi: 10.1016/j.cvdhj.2020.06.004. Epub 2020 Aug 28. Erratum in: *Cardiovasc Digit Health J*. 2021;2(2):150-151. doi: 10.1016/j.cvdhj.2021.03.006. PMID: 34386784; PMCID: PMC8357265.
24. Kheirkhahan M, Nair S, Davoudi A, Rashidi P, et al. A smartwatch-based framework for real-time and online assessment and mobility monitoring. *J Biomed Inform*. 2019 ;89:29-40. doi: 10.1016/j.jbi.2018.11.003. Epub 2018 Nov 7. PMID: 30414474; PMCID: PMC6459185. (accessed: 18/02/2025).
25. Who Owns the Data Collected by Wearable Devices? <https://dotsecurity.com/insights/blog-who-owns-data-collected-by-wearable-devices>. (accessed: 09/08/2025).