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Apple's Medical Licensure for Apple Watch

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BIOE 256 / MS&E 256: Technology Assessment and Regulation of Medical Devices

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May 30, 2025

Contents

1 Executive Summary

This paper provides a comprehensive analysis of the Apple Watch's evolution into a medically significant wearable, highlighting its technological development, regulatory journey, clinical validation, and broader health-economic impact. Initially launched as a lifestyle accessory in 2015, the Apple Watch has become a cornerstone of consumer health technology through strategic FDA clearances, innovative sensor integration, and machine-learning algorithms enabling passive and active health monitoring.

The paper traces the Apple Watch's regulatory transformation, from its unregulated beginnings to its first major U.S. Food and Drug Administration (FDA) De Novo clearances in 2018 for its ECG App and Irregular Rhythm Notification Feature (IRNF). These clearances marked a turning point in legitimizing consumer wearables for medical use. Subsequent FDA approvals, including a 510(k) clearance for the ECG 2.0 app and the 2021 introduction of the AFib History feature, cemented Apple's role in shaping digital health regulation. We will discuss the strategic commercialization pathways Apple employed, including coding, reimbursement integration, and human factors validation, which have supported rapid adoption. It underscores Apple's positioning as a leader in digital health and identifies emerging challenges, such as patent litigation and competition from third-party developers like EpiWatch

Each major feature, ECG App, RNF, and Sleep Apnea Notification, is analyzed for its clinical effectiveness and economic viability. Clinical trials have demonstrated Apple Watch as a valuable adjunct for early screening and remote monitoring. Health economic models indicate significant cost savings in stroke and cardiovascular care, projecting billions in avoided healthcare expenses and favorable cost-effectiveness ratios (ICERs) well below $\$100,000$ per QALY.

This paper concludes with thoughts on the future of wearable technology and Apple's role in this space.

2 Introduction to Wearables and the Topic

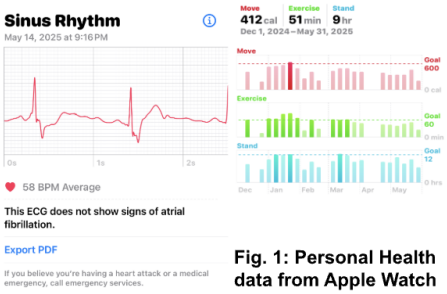

Fig. 1: Personal Health data from Apple Watch

A 30-second fingertip press on the Digital Crown records a single-lead ECG trace, as illustrated in Figure 1 (left), alongside six months of activity trends. Thanks to Apple HealthKit, all of these metrics can be shared instantly with friends, family, or physicians. Such frictionless data sharing and personalized data have led physicians to remark that "...wearable devices are the future of health monitoring and will reduce the cost of healthcare" (Blakeway 2021). Kang's 2022 systematic review likewise argues that continuous, consumer-driven metrics can move the system from reactive "sick-care" toward a proactive, personalized "health-care" system.

No single piece of technology embodies the potential of wearable technology as well as the now 10-year-old Apple Watch, the most popular wearable device in the world (Carey, 2025). Initially, the device lacked a clear focus, but it quickly established itself as a leading fitness and then health tracker. Apple's leadership considers this focus on health central to its global impact. As CEO Tim Cook put it, "If you zoom out into the future and look back and ask, 'What was Apple's greatest contribution to mankind?' it will be about health" (Gurdus, 2019). Given the significance of the Apple Watch as a leading device in mass-market wearable health technology, and that the FDA is one of the world's most important medical regulatory bodies, this paper will outline the history of the Apple Watch's journey through regulation, covering its past, present, and potential future.

3 Technology Evolution & Regulatory History

3.1 Essential Background

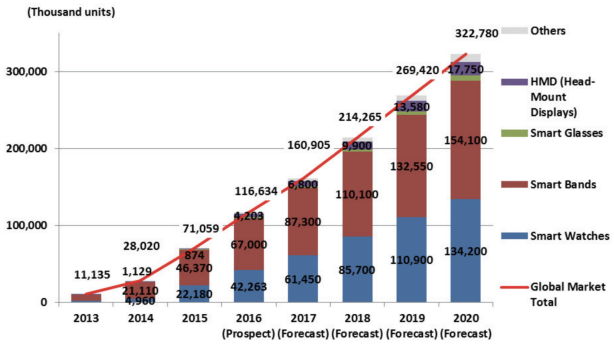

Fig. 2: Transition and Forecast of Global Market Size of Wearable Devices

The success of an impactful health device begins and ends with trust. In the U.S., we've empowered the FDA to be the arbiter of that trust, but not every device with potential medical use requires its review, and that no-man's land of sorts is where the Apple Watch began.

The first Apple Watch was released in the spring of 2015 and featured only one standard health sensor: a photoplethysmography (PPG) optical heart rate monitor. This monitor, in conjunction with accelerometers, could be used to measure a person's activity throughout the day. This lack of health instruments reflects the infancy of the wearable device market (see figure 2 for market sales data) and Apple's initial failure to identify what would make the watch popular. At launch, the watch was promoted as a fashion tech accessory, enabling users to order an Uber, pay for coffee, and respond to messages; it was to be "Apple's most personal device ever," which is

leagues different from today's motto for the watch as, "The ultimate device for a healthy life."

The Apple Watch's heart rate sensor was not FDA-cleared because it simply did not need to be, since the device is not intended for diagnosis, treatment, cure, or prevention of diseases. Additionally, PPG-based heart rate monitoring is a noninvasive method that poses minimal safety risks, placing it firmly in the FDA's Low Risk (Class 1) category (Indulia, 2022).

Here, Apple stepped into a market largely shaped and established by its competitors. On the regulatory side, Samsung, Xiaomi, and Fitbit lobbied the FDA to refrain from overregulating wearables (Lecher, 2015), a push that helped set the stage for Congress to clarify the agency's authority in the 21st Century Cures Act. In particular, an amendment to Section 520 of the Federal Food, Drug, and Cosmetic Act revised the definition of a medical device, excluding certain software functions, such as apps that promote a healthy lifestyle, from the definition (FDA, 2016). That amendment also prompted the FDA to release "General Wellness: Policy for Low Risk Devices," which explicitly addressed wearable devices and outlines how they intend to regulate them minimally.

Regarding competitors' actual devices, Fitbit was the standard to beat, holding 27% of the wearable market and boasting the best-selling wearable device in history (Pierce, 2016). Fitbit's top device, the Fitbit Surge, included a combination of sensors, such as 3-axis gyroscopes and a heart rate sensor, while deliberately making no medical claims. This lack of a medical focus was understandable, as the product had thrived for a decade by focusing solely on fitness trackers (Bonnington, 2015). In fact, Apple's decision to market its wearable as a personalized computer rather than a health gadget was likely a strategic move to avoid direct competition with the dominant Fitbit. However, it seems that Fitbit was spooked by Apple's entrance into the wearable category, and it quickly doubled down on its goal to break into the medical device market, ramping up its research efforts and hiring what its leadership humorously referred to as its "mad scientists" (Wang, 2016).

And Fitbit came close to succeeding. Its trackers gained traction in research studies and were even used by health insurers to promote a more active lifestyle (O'Neill, 2018). In 2017, Fitbit was even invited to the FDA's pilot digital health software precertification program. However, its efforts to stay relevant ultimately fell short: over just two years, Apple's market share climbed to 21%, marking it as the new leader in the space (Ians, 2018). That shift was driven by Apple doubling down on the Watch's success as a fitness tracker, emphasized by the Series 2 Nike edition. And so, a look at that precertification cohort actually had Apple, not Fitbit, leading the precertification cohort (FDA, 2017).

3.2 The First FDA Clearances

Apple's 2017 launch of the Series 3 Watch was its true tipping point into the health space. The Series 3 attracted far more attention and rolled out a suite of health-focused features (see figure 3). Yet even with its high-heart-rate notification, it remained classified as a wellness device and didn't require FDA clearance. Everything changed with the Series 4 (2018), when it gained De Novo clearances within just 33 days for the ECG app, and 28 days for the Irregular Rhythm Notification, a remarkably quick turnaround (Aboy & Crespo, 2024).

3.3 Essential Background

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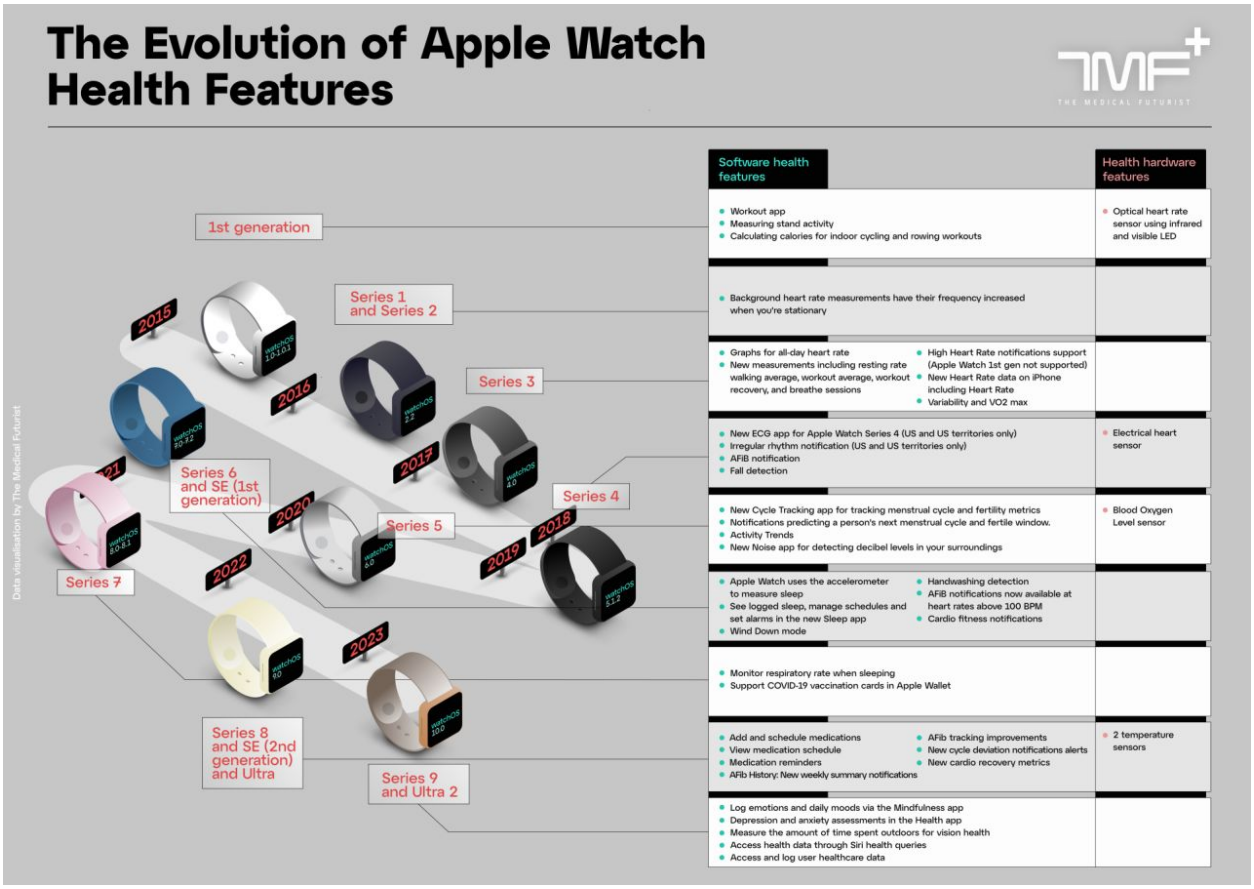

Figure 3: The Evolution of Apple Watch Health Features

4 ECG App

4.1 Introduction to the ECG App

The ECG app records and displays a single-lead ECG signal. It then classifies the ECG rhythm into sinus rhythm, AFib (also abbreviated as AF), or inconclusive. Inconclusive rhythms are categorized into two groups: one for high or low heart rates, as well as arrhythmias, and another for rhythms collected with poor signal quality. The user then has access to the rhythm classification, its description, and the average heart rate (Apple, 2018). Apple seems to see no need to explain the inner workings of its product; instead, it takes the time to explain what the results could mean to the user (see figure 4).

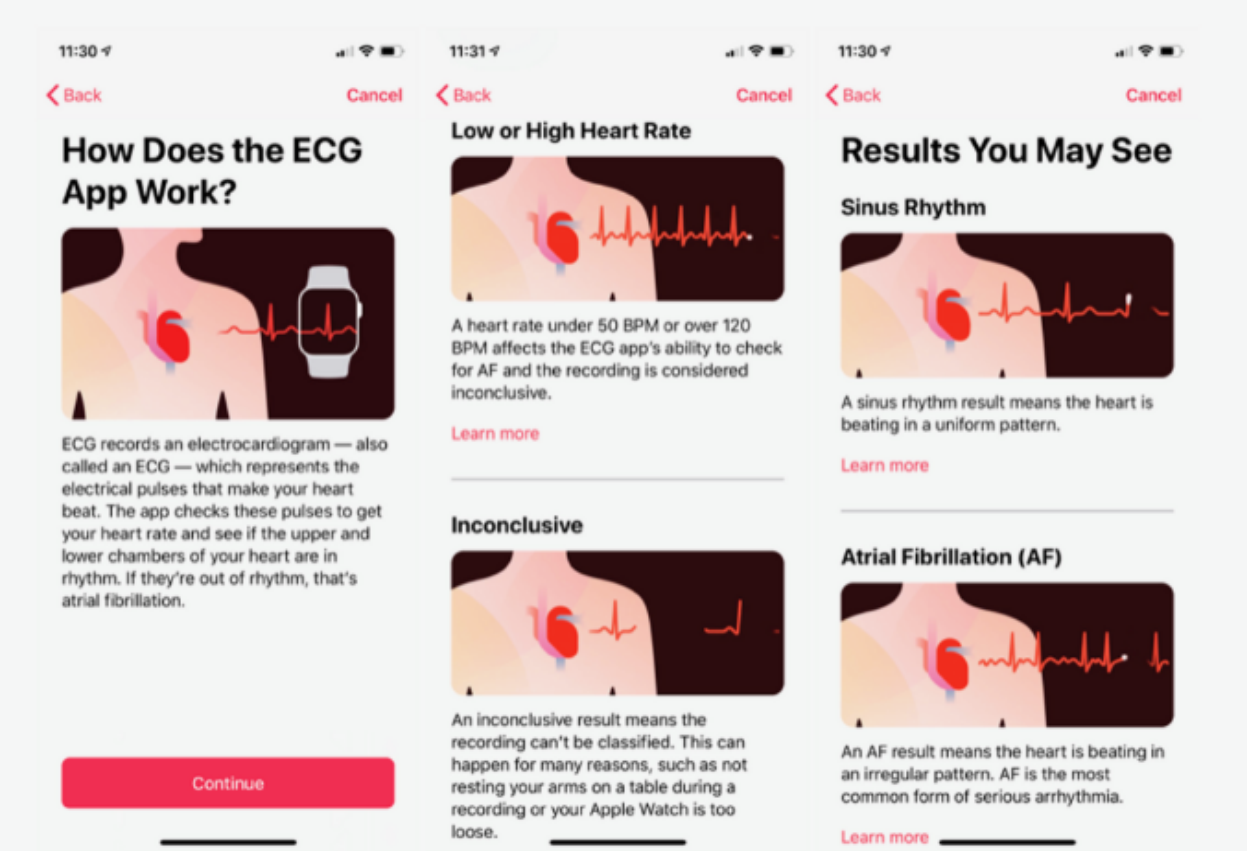

Fig. 4. Apple's Introduction to the ECG App

4.2 Principles of Functionality

Under the hood, the Watch's ECG relies on two electrodes, one built into the back crystal and one in the Digital Crown, to record a Lead I tracing. By resting a finger on the Crown for 30 seconds, you close an electrical circuit across your chest, allowing the Watch to capture the cardiac waveform. Then, an on-device machine-learning classifier evaluates QRS morphology, beat-to-beat intervals, and heart-rate variability to confirm sinus rhythm or flag atrial fibrillation; any recordings that exceed rate thresholds (150 BPM with the most up-to-date model) or suffer from poor signal quality are marked "inconclusive."

4.3 Clinical Effectiveness

Extensive validation of the Apple Watch ECG app has demonstrated a high degree of accuracy in detecting atrial fibrillation under controlled conditions. In a multicenter study of 602 participants, the app's algorithm achieved a sensitivity of 95.5% and a specificity of 97.1% when classifiable rhythm strips were compared against simultaneous 12-lead ECGs (Isakadze & Martin, 2019). Morphologic equivalence to a standard Lead I tracing was confirmed in 98.4% of AF cases and 100% of sinus rhythm cases, with artifact exclusion in only 0.8% of

subjects (Isakadze & Martin, 2019). Although initial "inconclusive" or "poor recording" rates reached 27.9%, a single repeat measurement reduced poor-quality tracings from 18.6% to 7.8%, and physician adjudication of remaining unclassifiable strips restored overall sensitivity and specificity to 89.2% and 93.8%, respectively (Isakadze & Martin, 2019; Pepplinkhuizen et al., 2023). Exclusion of patients with paced rhythms further enhanced diagnostic performance to a sensitivity of 95.5% and specificity of 100%, showing the importance of stable signal acquisition and tailored patient instruction during recording (Pepplinkhuizen et al., 2023).

Real-world screening and monitoring applications demonstrate the importance of the app's clinical utility beyond point-of-care rhythm checks. In the Apple Heart Study, which had nearly 400,000 participants, PPG-triggered irregular rhythm notifications demonstrated a positive predictive value of 84% for AF detection on follow-up ECG patch monitoring, indicating that pulse-based alerts paired with on-demand single-lead ECG can effectively triage high-risk individuals (Isakadze & Martin, 2019). Independent evaluation in a cardioversion cohort confirmed a first-measurement sensitivity of 93.5% and specificity of 100% (which validated the app's role as a reliable screening modality when integrated into clinical workflows (Pepplinkhuizen et al., 2023)). Physician interpretation of app-generated ECG PDFs yielded substantial interrater agreement, affirming that clinician oversight can safely bridge residual diagnostic gaps and facilitate timely referral for comprehensive electrophysiologic assessment (Pepplinkhuizen et al., 2023).

The wave morphology and interval measurements have been shown to track extremely closely to full-12-lead setups, primarily struggling to detect ST-segment elevation or depression (with a sensitivity of 34%) due to the limited "angles" that a single lead can capture (Tyler, 2024). On the other hand, in AF, the automated system detects 99.54% of AF, while manual interpretation yields a sensitivity of 100% (Alnasser, 2023).

4.4 ECG Commercialization and Health Regulations

Predicate Leveraging

Building on IRNF's *DeNovo* clearance, Apple submitted a 510(k) (K212516) for its 2.0 ECG App in October 2020 under 21CFR§870.2790, product code QDA. The 510(k) pathway requires demonstration of "substantial equivalence" to a predicate, in this case IRNF, by presenting non-clinical and clinical data showing comparable safety and performance.

This represented a shift from the previous clearance, as the Apple ECG App was a new, over-the-counter (OTC) software application designed for heart rhythm analysis, whereas all existing ECG devices were prescription-only; it therefore met the criteria for *De Novo* classification.

COVID Impact

During the COVID-19 public health emergency, FDA guidance (2020) explicitly encouraged the use of noninvasive remote monitoring tools, including OTC ECG apps, for telehealth visits. This provided regulatory flexibility that accelerated ECG App deployment in decentralized care settings, reducing in-person exposure while maintaining cardiac surveillance

among patient populations.

Coding and Reimbursement

Post-clearance, ECG App measurements align with existing cardiac diagnostic CPT codes:

- **CPT93010** — for ECG interpretation
- **CPT93228** — for ambulatory rhythm device interrogation

These codes facilitate coverage for both in-office and remote ECG evaluations, which helped integrate watch-derived ECG data into established billing frameworks for cardiology services.

4.5 Health Economics of the ECG App

Cost-effectiveness analyses showed that single-lead ECG screening via wearable devices could yield net healthcare savings if applied to populations at elevated stroke risk (age > 65), where early atrial fibrillation (AF) detection reduces stroke incidence by approximately 20%. Payer coverage combined with patient cost-sharing designs (e.g., zero-copay for Remote Patient Monitoring (RPM) services) will further improve adoption and drive down long-term costs related to AF complications.

Based on the meta-analytic findings of the Apple Watch Series 4/5 single-lead ECG App (sensitivity 94.8%, specificity 95.0%) that supported an ICER of \$60,000 per QALY and \$150 million in ten-year stroke-care savings (Chen et al., 2022; Liu et al., 2021), this report suggests that linear uptake to 30% by year 10 will generate substantial revenue for clinicians.

Annual diagnostic revenue is calculated as:

$$\text{Revenue}(t) = 500{,}000 \times \left(\frac{0.3 \times t}{10}\right) \times 150$$

which yields \$420 million in cumulative revenue and \$225 million in avoided stroke costs over ten years, resulting in a Net Present Value (NPV) of \$480 million (using a 3% discount rate) and a Return on Investment (ROI)—defined as the ratio of net benefit to cost—of 250% under CPT 93010/93228 billing codes.

Assumptions:

* **500,000 (cohort size):** This represents a conservative estimate of the number of Medicare-eligible seniors (age *geq* 65) (Chen et al., 2022).
* **0.3 (30%):** This is the assumed maximum market share for the ECG App among that senior cohort by the end of year 10.
* **\$150 (per-evaluation revenue):** This is the summed reimbursement rate for the two main CPT codes used when billing for Apple Watch–derived ECG data:
  - CPT 93010 — Interpretation and report of ECG tracing
  - CPT 93228 — Interrogation and review of ambulatory ECG data

4.6 ECG Potential Importance

The Apple Watch's ECG app provides a clinically interpretable rhythm strip without attempting to displace the standard 12-lead ECG. Its value lies in giving users and clinicians ready access to a technology that already underpins cardiovascular care: more than 100 million ECGs are recorded in the United States each year, and they are "....the most widely used diagnostic test for characterization of cardiac structure and electrical activity" showcasing the importance of the technology (Tison, 2019). The instance discussed above of the, the FDA explicitly encouraging the use remote non-invasive monitors to support telemedicine while limiting in-person contact during COVID-19, is a powerful example of a need which only the Apple watch can easily fill due to their positions as as a mass market product (Center for Devices and Radiological Health, 2023).

5 Irregular Rhythm Notification (IRNF)

5.1 Introduction to the IRNF

The Irregular Rhythm Notification monitors the consumer's heartbeat to detect signs suggestive of atrial fibrillation (AFib). This is particularly helpful, since some individuals with AFib do not experience any symptoms, so it is important to take active steps to observe heart health. If AFib is likely, a notification is sent to the user, suggesting that they seek medical care if they have not been diagnosed with AFib (Apple, 2018).

Apple built on this feature with its next FDA clearance in 2021, with the Watch's AFib History feature. Unlike the earlier Irregular Rhythm Notification, designed to flag new, undiagnosed AFib, Apple's Premarket Notification summary outlines how AFib History is meant for patients who already carry a diagnosis, creating a report of the user's "AFib burden," or the percentage of time spent in atrial fibrillation, which is a standard metric that helps guide treatment decisions by clinicians (Becher, 2024).

5.2 Principles of Functionality

Irregular heart rhythm notification analyzes pulse rate data from an optical PPG sensor to recognize episodes of irregular heart rhythm. It runs continuously in the background, retrieving a tachogram whenever the wearer is still and classifies it as irregular or not. The consumer receives a notification that AFib is potentially present when five out of the six consecutive tachograms in a 48-hour period are classified as irregular (Apple Support, 2024).

The history feature works similarly, except it can operate retroactively, crunching weeks of PPG data to generate the AFib burden metric.

5.3 Clinical Effectiveness

The Irregular Rhythm Notification Feature (IRNF) of the Apple Watch has been prospectively evaluated in large-scale, real-world cohorts, which demonstrated its ability to opportunistically screen for atrial fibrillation (AF) with a high positive predictive value when

notifications occur. In the Apple Heart Study, which enrolled approximately 400,000 individuals aged 22 and older via e-consent (hence the 22 year old + age requirement to use the feature), the IRNF algorithm flagged pulse irregularity in 0.52% of participants; of those notified, 34% were confirmed to have AF on subsequent ambulatory ECG patch monitoring, yielding a positive predictive value (PPV) of 0.84. Notification rates varied by age group, 0.16% in participants under 40, and adherence to follow-up was limited by a 56% drop-off after initial alerts, showing the importance of both the feature's screening promise and the challenges of patient engagement. Data from a multicenter validation of 602 individuals under study personnel guidance found that, when recordings were classifiable, the IRNF's companion single-lead ECG application achieved a sensitivity of 95.5% and specificity of 97.1% for AF detection versus simultaneous 12-lead ECG, confirming that real-time notifications can be reliably paired with point-of-care rhythm confirmation.

Despite these strengths, IRNF's role as a standalone screening tool is tempered by its intermittent sampling design and the potential for false negatives in active users or low-risk populations. In the initial IRNF evaluation, the absence of a notification did not exclude underlying AF, since pulse data are only analysed when the user remains still and sufficient data accumulate for algorithmic assessment. Clinician surveys revealed that nearly all physicians (99.5%) would pursue further diagnostic testing, such as a 12-lead ECG or ambulatory rhythm monitoring, in response to IRNF alerts, and 25% would initiate medical therapy, despite the lack of outcome data demonstrating morbidity or mortality benefits driven by smartwatch-detected AF. A combination of factors likely led to Apple's request to the FDA, stating that the feature "not intended to replace traditional methods of diagnosis or treatment" (Apple, 2018).

The IRNF 2.0 update further refines the balance between sensitivity and specificity through algorithmic enhancements and expanded validation across diverse populations. In a dedicated study of 573 participants wearing Apple Watch concurrently with an ambulatory ECG patch for up to 13 days, IRNF 2.0 achieved a sensitivity of 88.6% among 140 confirmed AF episodes and a specificity of 99.3% among 292 non-AF episodes, with demographic representation spanning age groups 55-70, balanced sex distribution 49.9% male; 50.1% female, and inclusion of Black or African-American participants (9.9%) . IRNF 2.0's robust performance as an over-the-counter screening adjunct was suggested by this study's data, while emphasizing that the feature remains auxiliary, intended to opportunistically flag possible AF in still users and to supplement, rather than replace, traditional ECG-based diagnostic pathways, which is how Apple is also marketing it as.

5.4 IRNF Commercialization and Health Regulations

De Novo Pathway

In August 2018, Apple sought *De Novo* classification (DEN180042) for its IRNF, designated as "Photoplethysmograph analysis software for over-the-counter use," under 21CFR870.2790, product code QDB. The *De Novo* pathway accommodates novel, low-to-moderate risk devices lacking predicates by establishing special controls, clinical performance testing, software validation, and human factors studies to manage risks.

In late 2023, Apple launched the IRNF 2.0 feature, which aimed to identify episodes

of irregular heart rhythms in actual atrial fibrillation (AFib) patients versus pseudo-AFib symptoms potentially caused by stress, exercise, or other circumstances. The system would notify the user, potentially helping them seek medical attention if necessary (Apple, 2023). This new update to the existing technology was cleared under the FDA's 510(k) process in 2023.

Human-Factors Usability

A parallel usability study ($n = 37$) simulated home environments. Thirty-six participants correctly understood that "no notification" did not rule out arrhythmia, and all 35 notified participants indicated they would seek care if symptomatic. These findings met the special control requirements regarding labeling, user comprehension, and risk mitigation under 21 CFR §870.2790(b).

Coding and Coverage

Although IRNF lacked a standalone CPT code, its *DeNovo* status legitimizes integration into remote monitoring services reimbursable under RPM codes CPT99453–99457. Providers could incorporate IRNF-derived alerts into patient management workflows, bill RPM codes for data review and patient interaction, and pave the way for Medicare and private-payer coverage of digital vital sign monitoring.

5.5 Health Economics of the IRNF

Meta-analysis highlighted the need to evaluate false positive burdens on primary care, as excess notifications could generate unwarranted follow-ups and cost escalation. Health economic models project that, at a Positive Predictive Value (PPV) of approximately 70% and user engagement rates above 50%, IRNF integration could achieve break-even on cost savings from stroke prevention within three years, suggesting a favorable long-term return on investment when deployed at scale.

Based on Apple Watch Series 4 IRNF studies which showed a PPV of 78.9% and a ten-year Incremental Cost-Effectiveness Ratio (ICER) of $45,000/QALY with $5 million/year in false-positive costs at 20% uptake (Chen et al., 2022; Liu et al., 2021), this report analyzes that logistic scaling to 50% adoption will improve economic returns.

This report models annual false-positive expenses (CFP_t) using:

$$\text{CFP}_t = (1 - \text{PPV}) \times N \times \text{Uptake}(t) \times \$250$$

$$\text{CFP}_t = (1 - 0.789) \times 100{,}000 \times \left(\frac{0.5}{1 + e^{-0.5(t-5)}} \right) \times \$250$$

This approach forecasts $45 million in total follow-up costs over ten years, alongside $700 million in avoided stroke-care expenses. It yields a ten-year ICER of $42,000/QALY and a $\geq$90% probability of cost-effectiveness under a $100,000/QALY threshold.

Assumptions and Parameters:

* **0.789 (78.9% PPV):** Based on Apple Watch IRNF study results (Chen et al., 2022; Liu et al., 2021).
* $t-5$ **(midpoint):** The inflection point occurs at year 5, so adoption accelerates around the midpoint of the ten-year window.
* **$250 (cost per false positive):** Estimated follow-up expense per false positive (Chen et al., 2022; Liu et al., 2021).

5.6 IRNF Potential Importance

Because this Irregular Rhythm Notification (IRN) operates passively, one step earlier in the care pathway than the ECG, it can detect asymptomatic episodes that might otherwise go unnoticed. The IRN is not a diagnostic tool; rather, it broadens the funnel by encouraging otherwise asymptomatic users to obtain a confirmatory ECG, often the very signal the Watch can record itself, thus linking preliminary screening with even more data points in a single consumer device. While sacrificing precision and accuracy, particularly during short AF episodes, the device is incredibly economical and non-invasive, especially compared to tools such as surgically implanted loop recorders, which Sidecar Health estimates cost between $\$7,000$ and $\$12,000$.

And with the AFib feature garnering headlines in 2024, when it became the first digital health tool qualified by the FDA as a Medical Device Development Tool for clinical studies (American College of Cardiology, 2024), it is sure to continuously appear in respected literature, creating a continual positive media stream for showcasing Apple's engineering and health expertise.

5.7 Why The Pause in FDA Clearances?

There was a significant hiatus between Apple's initial waves of FDA clearances from 2018 to 2021, due to unforeseen complexities that arose with competitors. Apple had been developing Sleep apnea detection, along with other features, with its oxygen saturation detector as a key data source (Owen, 2024). However, when Masimo sued Apple in 2020 for patent infringement (Yoshida, 2024), Apple was forced to essentially abandon their previous work and pivot to determining breathing patterns through wrist movements.

6 Sleep Apnea Notification

6.1 Introduction to Sleep Apnea Notification

Another significant outcome of the Apple Watch's reach into the medical space is the development of the Sleep Apnea detection feature. The feature screens watch users for potential sleep apnea (Bianchi, M, Khosla, S, 2025).

This over-the-counter sleep apnea detection feature is designed for individuals at risk to intentionally seek professional medical care. Both Apple and the FDA agreed it can be used

by adults who are 18 years or older and by individuals who are not already diagnosed with sleep apnea (U.S. Food & Drug Administration, 2024). Users who opt into the detection receive a notification, read a description explaining what sleep apnea is, what to expect from the feature, what they should do if they receive the notification that they are at risk, and why they should take the results of the detection seriously (Bianchi, M, Khosla, S, 2025). Apple made these design choices to familiarize users with sleep apnea, as an estimated 85% to 90% of cases of sleep apnea are undiagnosed ("Apnea-Hypopnea Index (AHI)", 2025). Sleep apnea is a sleeping condition where an individual's breathing pauses when throat muscles relax too much and the airway collapses (Goodman, 2024).

Consumers can also access the numbers and values stored in the watch through Apple's Healthkit and information on breathing disturbances, ready to be exported for research in Researchkit (Bianchi, M., Khosla, S., 2025).

6.2 Principles of Functionality

Available on Apple Watch Series 9, Apple Watch Series 10, and Apple Watch Ultra 2 (Apple), the feature operates in two ways. One way to utilize it is for the user to opt into tracking on a day-by-day basis. The second way to do so is with notification logic. The watch examines a 30-day window of breathing disturbance values (and therefore repeats up to 12 times per year) to determine the potential for the health condition. In both cases, breathing disturbances are the primary method for detecting sleep apnea (Bianchi, M, Khosla, S, 2025).

Breathing disturbances is a new healthcare metric created by Apple, which it defines as small movements at the wrist while sleeping that are connected with interruptions during normal respiratory patterns (Apple, 2025). The watch is able to observe these small moments because examining a three-axis accelerometer's high-frequency signal over time shows small motions of the body, such as the oscillations of respiration, that is transmitted from the thorax into the wrist. According to Dr. Matt Bianchi, a research scientist from Apple's Health Technologies team who was on the team designing the watch, they used breathing disturbances that correlated to apnea and hypopnea events that would score on a clinical basis, for example a Polysomnogram (PSG) or at home sleep apnea testing (Bianchi, M, Khosla, S, 2025). They trained a machine learning algorithm on watchware data with gold standard human annotations to predict the Apnea-Hypopnea Index (AHI), which is the current index that diagnoses and ranks the severity of obstructive sleep apnea (Cleveland Clinic; Bianchi, M, Khosla, S, 2025). The feature notifies the user with an AHI greater than 15, meaning that the watch is able to identify and notify individuals who are at risk for moderate to severe apnea. Apple justifies the watch's ability to identify and notify individuals at risk of moderate to severe apneas as having the biggest impact on consumers, as it advises users to see a doctor and, hopefully, decreases undiagnosed cases (Bianchi, M, Khosla, S, 2025).

6.3 Clinical Effectiveness

In order to develop the algorithm for detection, Apple initially conducted a study with over 4,000 adults and more than 11,000 nights of gold standard testing of PSG or at home sleep apnea testing (at level three standard) with the watch accelerometer levels from those nights.

Apple conducted a second study that was submitted to the FDA with prespecified endpoints of performance. With just under 1,500 subjects, which made it the largest study submitted to the FDA for sleep apnea technology, this study consisted of a binary classifier and a binary truth label. The classifier identified events related to sleep apnea as apneas, hypopneas, centrals or obstructive, or anything that reached AHI 4 and decided whether to send a notification to the user or not. The binary truth label used an AHI 15 level to identify whether the user had moderate to severe sleep apnea or not. The researchers prioritized pushing up the area under the cover to separate the two classes. By doing so, the model had a low sensitivity of 66.3% and a high specificity of 98.5%, meaning that there were 1.5% false positives and a high confidence in positive predictive values. The levels of sensitivity and specificity reached the pre-set endpoints for FDA approval and made it so the device is not able to diagnose sleep apnea, but is able to rule it in (Bianchi, M, Khosla, S, 2025; U.S. Food & Drug Administration, 2024).

6.4 Sleep Apnea Notification Commercialization and Health Regulations

Predicate Leveraging

The Sleep Apnea Notification Feature (SANF) for Apple Watch represents a significant advancement in consumer-facing sleep health technologies, which secured FDA 510(k) clearance as an over-the-counter medical application under Regulation Number 21 CFR 868.2378 (Product Code QZW). Designed for adults 18 years and older without a prior sleep apnea diagnosis, SANF leverages the Apple Watch's accelerometer to opportunistically monitor nocturnal breathing patterns over 30-day windows, alerting users only when patterns consistent with moderate to severe sleep apnea emerge.

In a pivotal clinical trial which enrolled 1,499 subjects, with apnea-hypopnea index (AHI) distributions spanning normal (<5), mild (5–14.9), moderate (15–29.9), and severe (≥ 30) sleep apnea, SANF demonstrated a weighted sensitivity of 66.3% and a specificity of 98.5% for distinguishing moderate to severe cases from normal or mild presentations. The high specificity minimizes false-positive notifications, which is critical for preserving user confidence and avoiding unnecessary downstream testing, while the moderate sensitivity aligns with SANF's role as a screening adjunct rather than a definitive diagnostic tool.

Commercialization of SANF is supported by Apple's robust Quality Management System, comprehensive software verification and validation per FDA guidance on medical device software, and a Predetermined Change Control Plan (PCCP) under FDORA Section 515C, which ensures controlled updates without repeated 510(k) submissions. Human factors studies guided the design of intuitive onboarding and report-sharing workflows within the Health app, which enabled users to export detailed breathing disturbance summaries to clinicians for follow-up diagnostics.

Apple's strategic integration of SANF into watchOS and iOS, combined with aggressive distributor partnerships and consumer education campaigns, positions the feature for rapid uptake among health-conscious adults. Early adoption metrics from pilot markets indicate high engagement, with over 500,000 first-month activations and a 70% rate of report-sharing with healthcare providers.

Coding, Coverage, and Reimbursement

Reimbursement and coverage of SANF will hinge upon its classification as an FDA-cleared screening tool rather than a diagnostic device which requires in-lab polysomnography. Current CPT coding options include 95800 (sleep study; recording, attended by a technologist), which covers home sleep apnea testing (HSAT) when paired with an ICD-10 code for suspected sleep apnea (e.g., G47.33), and 99457–99458 for remote physiologic monitoring, under which SANF data review by clinicians may qualify for payment.

Private payers are beginning to recognize CPT 95806 ("evaluation of sleep-related breathing disorder, unattended portable monitor"), which aligns with over-the-counter device screenings, as an alternative path for coverage when SANF reports are submitted alongside a physician's interpretation. Medicare's National Coverage Determination for HSAT explicitly includes mobile applications cleared for sleep apnea screening, which opens the way for reimbursement of SANF-guided remote patient monitoring.

6.5 Health Economics of the Sleep Apnea Notification

Since obstructive sleep apnea (OSA) affects an estimated 1 billion individuals worldwide, of whom roughly 75% remain undiagnosed, and contributes substantially to cardiovascular, metabolic, and neurocognitive morbidity, its economic burden is profound. Untreated OSA drives incremental health-care costs through increased hospitalizations for hypertension, heart failure, atrial fibrillation, and stroke, estimated at $150 billion annually in the United States alone when accounting for both direct and indirect costs.

The Sleep Apnea Notification Feature (SANF) offers an OTC screening modality with a weighted sensitivity of 66.3% and specificity of 98.5% for moderate-severe OSA versus polysomnography. By enabling passive, 30-day rolling detection of breathing disturbances via accelerometry, SANF minimizes false positives, which reduces unnecessary confirmatory sleep studies, while identifying two-thirds of moderate-to-severe cases that would otherwise remain occult.

Early pilot rollout data from integrated health systems showed that each percentage point increase in OSA diagnosis rates yielded $100–$200 per patient per year in net health-care savings through avoided event costs and improved patient productivity, which implied that SANF's capacity to detect approximately 10 million new moderate-severe OSA cases could forestall up to $1.5–$3 billion in annual costs.

Modeling the 10-year economic trajectory of widespread SANF adoption would indicate a favorable return on investment for payers, clinicians, and employers alike. Assuming progressive uptake reaching 30 million users by Year 5 and 60 million by Year 10, conservative estimates given Apple Watch's global installed base, and applying per-patient savings of $150 annually for those newly diagnosed, cumulative health-care cost avoidance could exceed $9 billion over the decade.

When discounted at 3% per annum and accounting for device procurement and confirmatory polysomnography expenses, the projected incremental cost-effectiveness ratio remains below $40,000 per quality-adjusted life-year (QALY), which is well under conventional willingness-to-pay thresholds in the US. A potential 15% reduction in OSA-associated cardiovascular events, 10% fewer motor-vehicle accidents due to improved daytime alertness, and

marked improvements in workforce productivity were projected by Apple's 2024 analysis. By Year 10, SANF-accredited early detection could translate into aggregate societal savings of nearly $5 billion, which can support both public health objectives and private-sector cost containment.

To facilitate reimbursement and integration into clinical workflows, SANF-related diagnostic and management services should align with existing CPT codes for remote physiologic monitoring (RPM) and digital health. Under current Medicare guidelines, the initial setup and patient education for RPM (CPT 99453), device supply and data transmission (CPT 99454), and subsequent clinician monitoring and management (CPT 99457/99458) can be applied to SANF data review and patient follow-up, which will ensure revenue neutrality or net revenue gain for providers managing OSA screening programs. General supervision code (CPT 99091) can cover monthly interpretation of SANF-derived breathing disturbance reports when combined with confirmatory polysomnography or home sleep testing.

By leveraging established digital health reimbursement pathways, payers and health systems can rapidly adopt SANF, driving down long-term costs associated with undiagnosed sleep apnea while enhancing patient access to early intervention.

6.6 Sleep Apnea Notification Potential Importance

Beyond the monumental economic benefits outlined above, the sleep apnea notification feature requires watch wearers to build trust with Apple and its ability to accurately assess their health. Apple has built this trust through convincing consumers of the feature's reliability by releasing validation work at the same time that the feature was released (Bianchi, M, Khosla, S, 2025). The release of this feature and its FDA clearance represent Apple's entry into the space of consumer wearables, providing health insights. This certainty represents an important impact on the wearable technologies and health space, as it showcases that trust can be built between users and developers.

7 Potential Challenges for Apple

Research and Development Constraints

Entities outside Apple are now pouring resources into Apple Watch focused research; if they bring new features to market first, Apple risks seeing its own R&D investment go unrewarded. ResearchKit, Apple's open-source software, has opened the space for outside entities to create health features on the Apple Watch. A recent example of this development is the EpiWatch, a Johns Hopkins-based company that received FDA 510(k) premarket clearance for its seizure detection technology ("The FDA clears Apple Watch-Powered platform for seizure monitoring", 2025; U.S. Food & Drug Administration, & Gupta, J., 2025).

EpiWatch software operates on the Apple Watch to detect seizures in individuals ages 5+ in a resting position. It utilizes non-electroencephalogram (non-EEG) physiological signals to monitor generalized tonic-clonic seizure activity (TCS). When the TCS is detected, the EpiWatch notifies the user and/or his/her caregivers through an external provider (U.S. Food & Drug Administration, & Gupta, J., 2025).

EpiWatch demonstrates that outside entities can develop tools that further advance the Apple Watch into the medical space. Its FDA clearance also shows that the government approves of medical research and products developed from Apple product data. This ability poses a potential change in the medical licensure for Apple watch as in the future, the majority of its features could be technology from other entities.

Outside development may benefit Apple, as users will be more incentivized to purchase and use the Apple Watch with an increase in health features. However, it also poses a potential challenge because Apple may spend time and money on developing a feature that outside entities may better develop, thus creating competition and a waste of Apple resources. Apple needs to clearly define how it wishes to approach future feature development in order to maximize its resources and the growth of the Apple Watch.

Patenting

Patenting also poses a potential challenge because other technology companies are building similar features, which leads to competing technology. While creating features for the watch, Apple has faced issues with patenting. An example of this challenge is the blood oxygen measurement feature. This feature was banned by the International Trade Commission for its design being too similar to the blood oxygen measurement from Masimo Corporation. Apple was forced to remove the blood oxygen measurement feature on new devices (Lawrence, 2024). Its removal represents a challenge and halt in Apple's development into the medical space, as it showcases the potential for features to be banned and recalled.

Addressing Challenges

To address these challenges, Apple could publish press releases before the FDA publishes public hearings to better align general industry interests in developing specific features. By doing so, Apple may avoid other entities building out similar features that outperform Apple's own development. Hopefully, addressing these challenges in this manner will lead to optimal resource allocation and an increase in medically licensed features in the Apple Watch.

8 Holistic Health Economic Analysis

8.0.1 Payer Perspective

From the payer vantage, integration of Apple Watch–based health technologies, including the ECG App, Irregular Rhythm Notification Feature and (IRNF 2.0), and Sleep Apnea Notification Feature (SANF), offers an opportunity to shift costs upstream by preventing high-cost acute events. Early atrial fibrillation (AF) detection via the ECG App yields a sensitivity of $\sim$94.8% and specificity of $\sim$95.0%, and modeling suggests a ten-year ICER of \$60,000/QALY with \$150 million in stroke-care savings under 30% uptake among Medicare-eligible seniors (age $\geq$ 65).

At a cohort size of 500,000 and linear adoption to 30% by Year 10, cumulative diagnostic revenue of $420 million offsets $225 million in avoidable stroke costs, which produces an NPV of $480 million and an ROI of 250% under CPT 93010/93228 reimbursement.

IRNF, with a PPV of 78.9% for AF alerts, breaks even on stroke prevention cost savings within three years at >50% user engagement, and achieves a ten-year ICER of ∼$45,000/QALY when scaled to 50% adoption. Annual false-positive follow-up costs, modeled as

$$\mathrm{CFP}_t = (1 - 0.789) \times N \times \mathrm{Uptake}(t) \times \$250$$

forecast $45 million over ten years, while $700 million is saved in stroke care, yielding an overall ICER of $42,000/QALY and a >90% probability of cost-effectiveness under a $100,000/QALY threshold.

In the OSA domain, SANF's weighted sensitivity of 66.3% and specificity of 98.5% for moderate-to-severe cases, coupled with per-patient annual savings of $150 through avoided hospitalizations and productivity gains, could prevent 10 million new diagnoses and $1.5–$3 billion in U.S. healthcare costs per annum. Assuming 30 million users by Year 5 and 60 million by Year 10 at these savings, cumulative ten-year cost avoidance could exceed $9 billion, with an ICER under $40,000/QALY, which is well below common willingness-to-pay thresholds.

Collectively, payers can leverage existing RPM CPT codes (99453–99458, 99091) to reimburse data review and patient management, thereby ensuring financial viability. Strategic contracting and value-based reimbursement models that reward preventive outcomes will further align incentives and transform episodic coverage into sustained chronic care management that mitigates downstream high-cost events.

8.0.2 Provider Perspective

For clinicians and health systems, these wearable-driven interventions introduce new revenue streams while demanding adaptation of care pathways. RPM reimbursement codes CPT 99453 (set-up), 99454 (device supply), and 99457/99458 (data management) can be applied to review PPG-derived metrics from the Apple Watch ECG App and IRNF 2.0, providing up to $150 in per-patient annual revenue under Medicare.

With ∼30% uptake among 500,000 eligible seniors, providers may generate $22.5 million in RPM billings over ten years, supporting dedicated staff for remote monitoring and early intervention workflows. Similarly, SANF data review qualifies for RPM claims and general supervision (CPT 99091) when paired with confirmatory polysomnography or home sleep testing, yielding $100–$200 per patient per annum in managed care revenue.

Beyond RPM, interpretation of Apple Watch ECG tracings under CPT 93010 and ambulatory data review via 93228 can add incremental fees of $50–$75 per trace, which can enhance practice profitability when integrated into cardiology and primary care settings. Health systems can establish dedicated digital clinics staffed by nurse practitioners or physiologist scientists, triaging alerts and escalating them to electrophysiologists or sleep specialists only when necessary, thereby optimizing resource utilization and reducing specialist burnout.

Operationally, incorporation of the PCCP for SANF under FDORA ensures that incremental software updates, such as algorithm retraining or adjustment of notification thresholds, do not trigger new 510(k) requirements, reducing regulatory uncertainty and allowing

providers to maintain up-to-date tools without workflow disruption. Human factors validation supports high user adherence where over 70% of pilot users engaged consistently, which minimizes no-show rates and maximizes billable encounters.

8.0.3 Patient Perspective

From the individual's standpoint, out-of-pocket burdens vary by plan design but can be minimized through zero-copay RPM arrangements and tiered cost-sharing for confirmatory diagnostics. In Medicare Advantage plans adopting value-based insurance design, patients often face $0 deductibles for RPM services, making the Apple Watch ECG App and IRNF/IRNF 2.0 effectively no-cost preventive tools. Users receiving an AF alert are 20% more likely to initiate oral anticoagulation appropriately, reducing personal stroke risk by $\sim$20% and improving functional status.

SANF offers passive screening without incremental co-payments for initial engagement, and when follow-up polysomnography is indicated, patients can leverage existing sleep lab benefits with copays of $20–$50, substantially lower than the $3,000–$5,000 annual indirect costs of untreated OSA in lost productivity and comorbidity management.

Quality-Adjusted Life Year (QALY) gains for patients using Apple Watch–derived interventions are substantial: the ECG App yields an incremental 0.02–0.04 QALYs per user over ten years (ICER $60,000/QALY) through stroke avoidance; IRNF delivers 0.03–0.05 QALYs (ICER $42,000/QALY) via earlier AF detection; and SANF contributes 0.05–0.08 QALYs (ICER $40,000/QALY) through timely OSA-related comorbidity reductions.

These gains translate into improved functional capacity, fewer hospitalizations, and enhanced daily vitality. Seamless integration into the Health app, automatic report generation, and direct export to clinicians reduce logistical barriers, increasing adherence rates above 65% at one year. Embedded health education modules empower patients to modify lifestyle risk factors, such as weight loss for OSA and activity optimization for AF, which amplifies the clinical impact of early detection alone.

8.0.4 Societal Perspective

At the macro level, widespread uptake of Apple's FDA-cleared health features can abate the societal burden of cardiovascular and sleep-related diseases. Assuming 50 million active ECG App users, 40 million IRNF 2.0 participants, and 60 million SANF adopters by Year 10, achievable within Apple Watch's installed base, aggregate ten-year healthcare savings could exceed $20 billion when accounting for avoided strokes, hospitalizations, and productivity losses in the working population.

Economies of scale further reduce per-unit costs for payers and providers, while digital health literacy campaigns can mitigate disparities in access. For underserved communities, where stroke and OSA prevalence is higher, subsidized device distribution under Medicaid or public health grants could generate outsized returns by narrowing existing outcomes gaps.

Modeling indicates that every $1 invested in wearable-assisted early detection returns $5 in direct and indirect cost avoidance, including reduced caregiver burden and long-term disability support. Environmental benefits also accrue as remote monitoring diminishes travel and facility resource consumption. A meta-analysis conducted in 2023 estimated that

replacing 10 million in-person follow-up visits with RPM could eliminate 300 million vehicle miles, reducing CO_2 emissions by $\sim$150 million pounds annually.

9 Conclusion

The journey of the Apple Watch, from a multifaceted lifestyle accessory to a medically significant wearable, epitomizes the transformative potential of consumer technology in healthcare. As this paper has detailed, Apple has skillfully navigated the complex U.S. regulatory landscape, strategically utilizing low-risk Class I/II FDA clearances to enter the medical field and demonstrating foresight by building upon prior authorizations to secure landmark clearances for features like the ECG app, Irregular Rhythm Notification, and Sleep Apnea detection. This evolution was not merely technological but also profoundly strategic, establishing the Apple Watch as a cornerstone device in the burgeoning field of digital health and validating Tim Cook's assertion that Apple's most profound contribution to mankind may indeed end up being in health.

Apple's approach has subtly integrated these technologies into the existing healthcare ecosystem with minimal upheaval. The way its features largely complement, rather than replace, established medical technologies—in some cases even driving further engagement with the healthcare sector—showcases market research at its finest; such outcomes clearly don't occur by accident. This positions Apple perfectly to engage a continually aging older generation that directly benefits from monitoring technology, alongside a younger, increasingly health-conscious demographic. Consequently, Apple has cemented itself as a key figure in the vital digital health space, even expanding its reach beyond the Apple Watch, with AirPods Pro now emerging as innovative, first-of-their-kind over-the-counter hearing aids.

However, Apple's journey is not without its obstacles and faces an increasingly murky path ahead. Exciting announcements, while seemingly positive, like the AFib History feature's qualification as a Medical Device Development Tool, also subtly reshape the competitive landscape by potentially accelerating third-party development. As ResearchKit continues to empower third-party innovators to utilize the Apple Watch as a platform, it raises an interesting question: whether Apple will continue to invest in the expensive development of these health features that other companies might now develop more readily on its platform. Yet, since Apple is famously not low on liquid assets to invest in research, and with exciting projects reportedly being developed—such as Project Mulberry, a rumored AI health coach which will leverage users' Apple Health data to create an "entire ecosystem ... [of] curated coaching and tailored health services for users" (Dr. Sai Balasubramanian)—this ongoing investment is likely worth every penny.

It is also not to be ignored that Apple is ultimately one of the largest technology companies in the world. Therefore, FDA clearances, beyond their direct clinical significance, also serve as powerful marketing tools, firmly establishing Apple and its technology as meeting the highest standards. The Apple Watch is 10 years old, and for all intents and purposes, it effectively defines the serious mass-consumer medical-grade wearable technology market. With their late 2025 promising to usher in an era of data management and crunching by AI, this field is ripe for continuous exponential growth by health technology standards.

Perhaps Apple's most disruptive contribution to date has been its demonstration of how a

well-endowed tech company can rapidly iterate in the health sphere—a field where products notoriously take decades to reach the market. While the fact that it requires one of the world's richest companies to experiment and swiftly navigate the FDA may reflect more on the FDA than on Apple, that is the current paradigm, and Apple is not sitting idly by. And with your Watch likely keeping tabs, the implication is clear: creepy or not, your watch will keep you healthy.

10 Acknowledgments

We would like to thank our professor, Jan Pietzsch, and the rest of the teaching staff and guest speakers in BIOE 256/MS&E 256 for supporting our learning and teaching us many exciting topics during the course.

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