Hypertension Notification Feature on Apple Watch

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Overview

Apple Watch is a popular wearable device with many features designed to empower users to understand and improve their health. Since the launch of Apple Watch, heart health has been a foundational part of the watch and Health app experience, which includes heart rate measurements, high and low heart rate notifications, irregular rhythm notifications, the ECG app, AFib History, and cardio fitness tracking. Each of these features provides powerful insights, including notifications of abnormalities that may warrant medical attention. The Hypertension Notification Feature adds to the insights Apple Watch offers and specifically promotes awareness of chronic high blood pressure.

Hypertension Notifications — available on Apple Watch Series 9 or later and Apple Watch Ultra 2 or later (excluding Apple Watch SE) — helps users recognize if they are at high risk of hypertension. The feature works passively in the background during waking hours, analyzing data over discrete 30-day intervals to detect signs of hypertension. It does not require calibration, it does not measure blood pressure directly, and does not surface a blood pressure reading to users. Instead, the Hypertension Notification Feature notifies users if optical heart sensor data shows signs of hypertension after 30 days.

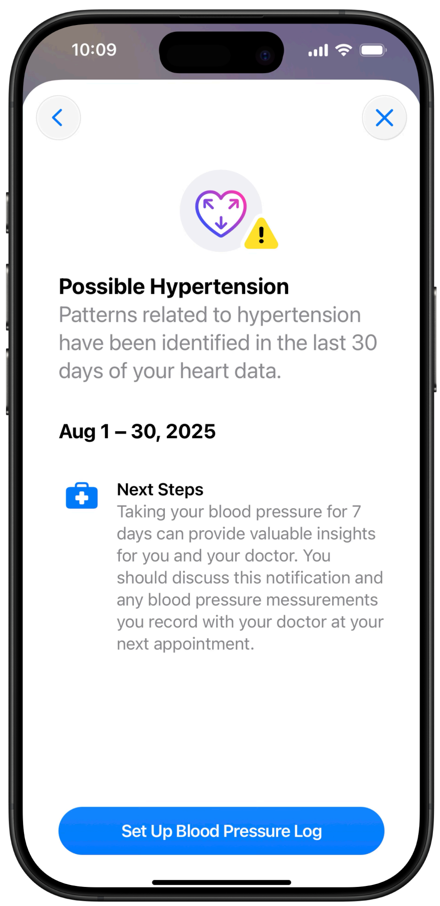
Hypertension Notifications is intended for people 22 years of age or older who have not been previously diagnosed with hypertension. It is not intended for use during pregnancy.

This paper details the development and validation of the Hypertension Notification Feature, developed by Apple using data from photoplethysmography (PPG), which measures blood volume changes through the skin and supports a wide range of Apple Watch features. The algorithm was developed using a large dataset from a diverse group of adults who participated in studies conducted or sponsored by Apple. The feature was then validated in a pivotal study to support regulatory submissions around the world.

Introduction

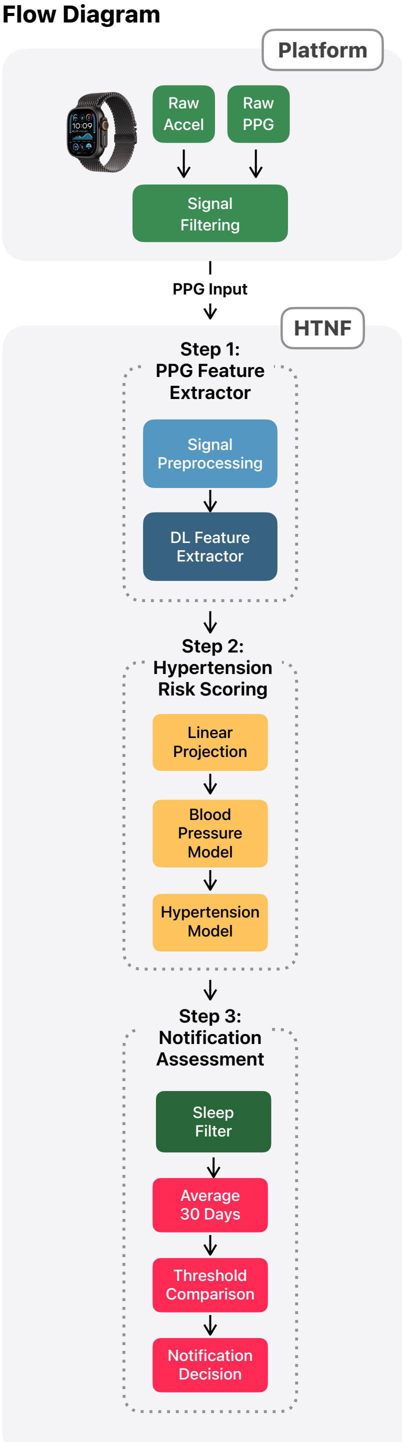
Hypertension — or high blood pressure — is a critical risk factor for long-term health outcomes,[1] affecting more than 1.3 billion adults worldwide.[2] Over time, untreated hypertension can lead to heart attack, stroke, kidney failure, and vision loss. It often goes undiagnosed for years because those affected rarely have symptoms, and single in-office blood pressure measurements can frequently miss detecting hypertension. Despite guidelines recommending routine hypertension screening, about half of adults around the globe who have hypertension remain unaware of it.[2]

Apple Watch helps address this diagnosis gap by passively monitoring for signs of chronic high blood pressure and alerting users who show patterns of hypertension — even when they are not actively checking their blood pressure or seeing a doctor. All they need to do is onboard the feature and wear their Apple Watch.



Machine Learning–Based PPG Analysis

Figure 1: HTNF Algorithm Flow Diagram



Technical and Feature Description

The Hypertension Notification Feature analyzes PPG data, which Apple Watch opportunistically collects to obtain information about how blood vessels respond to beats of the heart. Apple developed an algorithm using data from more than 100,000 study participants that examines PPG signals over 30 days to evaluate whether hypertension may be present. If signs are detected, users are notified of possible hypertension.

Preclinical Design and Algorithm Testing

Hypertension Notifications is powered by a machine learning–based algorithm to identify key PPG patterns that may indicate hypertension. The algorithm uses 60-second segments of PPG signals as inputs, collected approximately every two hours throughout nonoverlapping 30-day evaluation windows.

Before samples are processed, Apple Watch filters PPG data using accelerometer data to determine whether the user is sitting still, which is required for the algorithm.

The ML-based algorithm comprises three key steps, as shown in Figure 1:

Step 1: The **PPG Feature Extractor** transforms raw PPG data into generalizable characteristics that can be used to assess hypertension risk through layered models. The extraction uses a deep learning (DL) algorithm developed with a self-supervised learning method based on large-scale unlabeled data from the Apple Heart and Movement Study. Training data did not include any blood pressure or hypertension data, focusing solely on identifying PPG signal features.

Step 2: For **Hypertension Risk Scoring**, a set of linear machine learning models analyze distinctive features produced by the PPG Feature Extractor to score hypertension risk for each PPG segment. The dataset used to develop these models included PPG data and reference data collected from at-home blood pressure cuffs.

Step 3: In **Notification Assessment**, an algorithm determines whether a notification should be surfaced. First, hypertension risk scores are filtered to exclude samples collected during sleep, as the model was trained on PPG data from waking hours to reach the most users. Remaining scores are aggregated and averaged over each 30-day evaluation period, then compared against a threshold to decide if a notification should be sent.

Algorithm development was an iterative training and testing process involving multiple stages, including Validation and Test sets. After development, the algorithm was locked with no ongoing changes learned from new data.

To support the development of the algorithm, Apple conducted seven studies with participants representing a diverse range of demographic characteristics, including age, sex, body mass index (BMI), race, skin tone, ethnicity, and hypertension status. Table 1 below shows the characteristics of participants in the labeled training, validation, and test sets.

Table 1. Participant Demographics in Labeled Development Set

Demographic		Training	Validation	Test
Participants	*N*	3216	3878	2236
Sex	Female	54%	55%	57%
Age	18–39 years	40%	40%	32%
	40–59 years	37%	44%	53%
	≥60 years	23%	16%	14%
Race	White	51%	39%	45%
	Black or African American	18%	22%	34%
	Asian	21%	20%	15%
	Other/Unknown	10%	19%	5%
Ethnicity	Hispanic	14%	21%	16%
Fitzpatrick Scale	Type V and VI	13%	17%	20%
Body Mass Index	≥30 kg/m^2	31%	29%	42%
Hypertension	Stage 1 or 2	33%	33%	64%

A receiver operating characteristic (ROC) curve was generated based on the development data, and an operating point was selected to prioritize high specificity — minimizing false positives — while also notifying a significant portion of people with hypertension. To identify those at risk of developing hypertension over time, the algorithm analyzes their data after each 30-day period.

Usability and Design

Apple conducted eight human factors studies throughout development to optimize the user experience, including onboarding and notification language. These studies were invaluable in building an intuitive experience and were also included in regulatory submissions.

The Hypertension Notification Feature pairs with an updated blood pressure logging experience in the Health app, which can be used with a standard blood pressure cuff following a notification. It includes reminders to log blood pressure and classifications based on established guidelines from the American Heart Association (AHA) and the European Society of Cardiology (ESC). The log allows users to capture additional objective evidence that can support a clinician in diagnosis and can also reassure users who receive a notification but do not have hypertension.

Clinical Validation

Study Design

To demonstrate the safety and effectiveness of the Hypertension Notification Feature, Apple conducted a pivotal, decentralized clinical study including more than 2000 participants. This study was separate from and incremental to the validation steps outlined in the “Preclinical Design and Algorithm Testing” section. The validation study recruited adult participants who did not have a preexisting diagnosis of hypertension. Participants were enrolled in two cohorts: all-comers without known hypertension risk factors and those at risk of hypertension based on historical blood pressure values and other risk factors.

The study’s primary goal was to evaluate the algorithm’s performance in identifying users with hypertension. Performance was determined based on average blood pressure readings taken twice daily at home over 30 days using the reference device, the OMRON Evolv® Wireless Upper Arm Blood Pressure Monitor (Model BP7000, K162092). Subjects were instructed to wear Apple Watch for at least 12 hours each day and concurrently take blood pressure measurements with the OMRON Evolv for comparative analysis. Apple Watch passively and opportunistically collected PPG data throughout the study period, which was then processed by the Hypertension Notifications’s algorithm.

Table 2. Hypertension Categories Based on Home Blood Pressure Readings

HTN Category	Average SBP	Operator	Average DBP
Normal	<120 mm Hg	AND	<80 mm Hg
Elevated	120 to <130 mm Hg	AND	<80 mm Hg
Stage 1 HTN	130 to <135 mm Hg	OR	80 to <85 mm Hg
Stage 2 HTN	≥135 mm Hg	OR	≥85 mm Hg

Subjects took blood pressure measurements following AHA guidelines. The 30-day averages were categorized based on the 2017 American College of Cardiology (ACC)/AHA Blood Pressure Guidelines for home blood pressure readings.[3]

The validation study assessed the following coprimary safety and effectiveness endpoints:

- Notification sensitivity for participants with a Stage 1 or Stage 2 reference hypertension (HTN) category
- Notification specificity for participants with a Normal or Elevated reference HTN category

Study Results

The study enrolled 2229 subjects across all major blood pressure ranges and hypertension categories (Normal, Elevated Blood Pressure, Stage 1 HTN, and Stage 2 HTN). Participants represented a broad range of demographic factors including age, sex, BMI, and race and ethnicity subgroups, reflecting the intended user population. The Full Analysis Set included all enrolled participants, and the Notification Analysis Set included those with sufficient reference and investigational device data for use in the primary endpoint evaluation.

Table 3. Demographics in the Full Analysis Set and Notification Analysis Set

Demographic		**Full Analysis Set**	**Notification Analysis Set**
Participants	*N*	2229	1863
Sex	Female	43.1%	54.5%
Age	<55	64.0%	62.8%
	≥55 to <65	21.6%	21.8%
	≥65	14.4%	15.4%
Race Note: Subjects can select more than one race category.	Other	4.1%	3.8%
	White	69.4%	72.2%
	Asian	10.2%	10.9%
	Black or African American	20.4%	17.2%
Ethnicity	Hispanic	10.0%	10.1%
Fitzpatrick Scale	Type V and VI	15.1%	12.2%
Body Mass Index	>30 kg/m^2	37.1%	35.8%
Hypertension	Stage 1 or 2	27%	31%

Of the 2229 participants, 1863 met usable data requirements and contributed to the primary endpoint analyses. Those not included in the performance evaluation lacked sufficient Apple Watch or reference data or had major protocol violations. In the Notification Analysis set, 585 participants exhibited hypertension, while 1278 did not.

The overall sensitivity of the feature was 41.2% (95% CI [37.2%, 45.3%]), and the overall specificity was 92.3% (95% CI [90.6%, 93.7%]). Importantly, the specificity among those with normal blood pressure was 95.3% (95% CI [93.7%, 96.5%]). The sensitivity for Stage 2 hypertension, which is more severe and requires more aggressive management, was 53.7% (95% CI [47.7%, 59.7%]).

Table 4. Results

	Value	95% Confidence Interval
Sensitivity for Stage 1	90/304 (29.6%)	(24.5%, 35.1%)
Sensitivity for Stage 2	151/281 (53.7%)	(47.7%, 59.7%)
Overall Sensitivity	**241/585 (41.2%)**	**(37.2%, 45.3%)**
Specificity for Normal	924/970 (95.3%)	(93.7%, 96.5%)
Specificity for Elevated	255/308 (82.8%)	(78.1%, 86.8%)
Overall Specificity	**1179/1278 (92.3%)**	**(90.6%, 93.7%)**

Subgroup Results

Demographic subgroup analyses were conducted using unadjusted and covariate-adjusted point estimates, along with confidence intervals for sensitivity and specificity ratios across demographic categories. No prespecified statistical hypotheses were associated with these subgroup analyses; the subgroups and analyses, however, were prespecified.

Covariate-adjusted subgroup analyses were performed to account for demographic imbalances between subcategories. Analyses were adjusted for age, sex, body mass index (BMI), race, systolic BP average, and diastolic BP average.

The results of the unadjusted and adjusted subgroup analyses are illustrated in Figures 2 and 3. For each evaluated demographic characteristic, the subcategory listed first in parentheses serves as the numerator of the risk ratio. For example, a sensitivity risk ratio of 0.69 means the younger age group (<60) has a lower covariate-adjusted sensitivity than the older group (≥60). A specificity risk ratio of 1.09 means the younger age group has a higher covariate-adjusted specificity than the older group. Because a risk ratio of 1.0 indicates equal performance between subcategories, differences were considered nonsignificant if the 95% confidence interval included 1.0.

Figure 2. Demographic Subgroup Analyses of Sensitivity

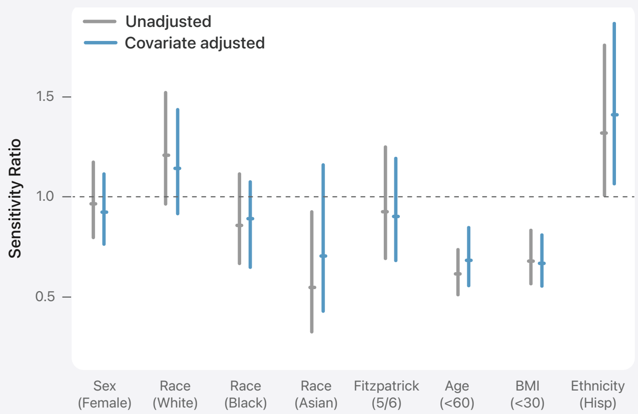
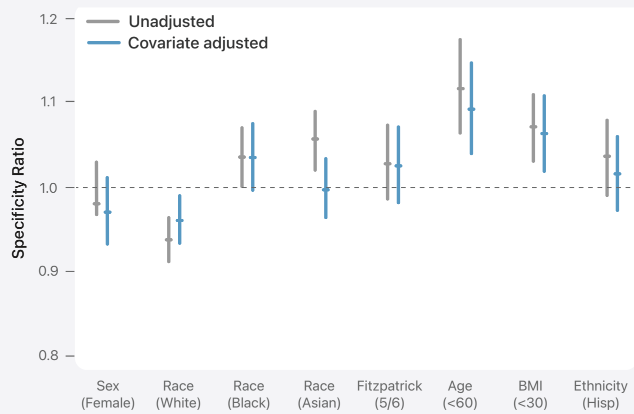


Figure 3. Demographic Subgroup Analyses of Specificity



Lower sensitivity and higher specificity were observed in those with younger age (<60) and lower BMI (<30). Importantly, comparisons of sex, race, and skin tone suggested no clinically meaningful difference after covariate adjustment. For example, the Asian subgroup was younger (mean age 43.0 vs. 50.9) and had lower BMI (mean BMI 27.7 vs. 30.9) compared with non-Asian participants. After covariate adjustment, Asian performance characteristics were on par with non-Asian participants.

Discussion

The clinical validation results demonstrated that the Hypertension Notification Feature can provide significant benefits to users. Unlike a screening or diagnostic test, this feature works opportunistically and passively in the background at the scale of a general-use consumer wearable. It notifies nearly half of users who have hypertension, and even more in the higher-risk Stage 2 hypertension category. This is important because long-term risks associated with hypertension — such as heart attacks, strokes, and kidney disease — increase with higher hypertension severity. To help prevent people with undiagnosed hypertension from over-relying on the feature, the onboarding process reminds users that not everyone with hypertension will receive a notification.

Specificity in the Normal category was 95.3%, indicating a significant portion of people alerted without hypertension actually had elevated blood pressure. This is important because the notification promotes awareness in users with elevated blood pressure, who may benefit from proactive conversations with their doctor and lifestyle changes to reduce long-term risk.

Comparisons among demographic subgroups showed higher sensitivity and lower specificity in users who were older or had a higher BMI, possibly reflecting more advanced disease or higher-risk vascular physiology. While alert rates will be higher in these groups, more proactive care and management is warranted.

Conclusion

Apple Watch offers many features focused on health and wellbeing. The FDA-cleared Hypertension Notification Feature — an important addition to the intelligent guardian features of Apple Watch — can alert users to possible hypertension after wearing their watch for just 30 days. It uses passive, opportunistically captured data right from users' wrists to detect signs of hypertension, which may otherwise be missed for years. With so many people already using Apple Watch for fitness, connectivity, safety, and other health applications, this feature could improve diagnosis rates, health management, quality of life, and longevity for those with hypertension.

[1]Whelton, Paul K., et al. "2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults," *Hypertension* 71, no. 6 (2018): e13–e115, doi.org/10.1161/HYP.0000000000000065. [2]World Health Organization, "Hypertension," *Newsroom Fact Sheets*, last modified April 1, 2023, who.int/news-room/fact-sheets/detail/hypertension. [3]Paul Muntner, et al. "Measurement of Blood Pressure in Humans: A Scientific Statement From the American Heart Association," *Hypertension*, 73, no. 5 (2019): e35–e66, doi.org/10.1161/HYP.0000000000000087.