Hypertension Notification Feature

Instructions for Use

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INDICATIONS FOR USE

The Hypertension Notification Feature (HTNF) is a software-only mobile medical application that analyzes photoplethysmography (PPG) data opportunistically collected by Apple Watch to identify patterns that are suggestive of hypertension and provides a notification to the user.

The feature is intended for over-the-counter (OTC) use by adults age 22 and over who have not been previously diagnosed with hypertension. It is not intended to replace traditional methods of diagnosis, to monitor hypertension treatment effect, or to be used as a method of blood pressure surveillance. It is not intended for use during pregnancy. The absence of a notification does not indicate the absence of hypertension.

PRECAUTIONS AND WARNINGS

The feature cannot detect a heart attack. If you ever experience chest pain, pressure, tightness, or what you think is a heart attack, call emergency services immediately.

The feature cannot identify every instance of hypertension. Regular blood pressure screenings are the most effective way to look for hypertension.

The feature cannot detect other conditions such as blood clots, stroke, atrial fibrillation, congestive heart failure, or high cholesterol.

The feature should not be turned on during pregnancy. The feature cannot detect preeclampsia or other hypertensive conditions related to pregnancy.

If you are not feeling well, you should talk to your doctor.

Apple Watch may be unable to collect data when Apple Watch is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

A number of factors can impact the ability of the feature to identify patterns of hypertension. These include factors like excessive motion, hand and finger movements, pigmentation such as dark wrist tattoos, environmental factors such as cold temperature that can cause reduction in the amount of blood flow to your skin.

DO NOT wear your Apple Watch during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

DO NOT change your medication without talking to your doctor.

Not intended for use by individuals under age 22.

Not intended for use by individuals previously diagnosed with hypertension.

Notifications made by this feature are potential findings, not a diagnosis of hypertension. All notifications should be reviewed by a medical professional for clinical decision-making.

Not all people with undiagnosed hypertension will receive a notification. The absence of a notification is not intended to indicate the absence of hypertension. You should notify your doctor if you experience any changes to your health.

For best results, wear and charge your Apple Watch regularly. Make sure it fits snugly on top of your wrist.

This feature has not been tested in those with paced rhythms or irregular rhythm such as atrial fibrillation, which may affect the performance of this feature.

CUSTOMER SUPPORT

This information and other labeling, including the user instructional brochure, are available on the internet at: [https://www.apple.com/legal/ifu]. You may also call Apple Support through the 'Contact Apple Support' option in the 'About Hypertension Notification Feature' screen or write to medicalcompliance@group.apple.com or One Apple Park Way, Cupertino, CA 95014 to request a paper copy of this information and other labeling.

As a user, you should report any serious incident that has occurred in relation to the feature to Apple

SECURITY

Apple recommends that you add a passcode (personal identification number [PIN]), Face ID to your iOS compatible device and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security. It is important to secure the iOS compatible device since you will be storing personal health information. Users will also receive additional iOS and watchOS update notifications on their devices, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. See "iOS and watchOS Security Guide" which describes Apple's security practices and is available to all of our users. For the iOS and watchOS Security Guide, please visit https://support.apple.com/guide/security/welcome/web.

In the event that you suspect or would like to report any security issues with your devices, please visit Apple's support webpage which describes how to get help with your security issues (https://support.apple.com/en-us/111756).

USING THE HYPERTENSION NOTIFICATION FEATURE

Getting Started

- For device compatibility information, please visit https://support.apple.com/117296.
- Update Apple Watch and iPhone to latest watchOS and iOS.
- Make sure your Apple Watch is paired to your iPhone.
    - For more information on pairing your Apple Watch to your iPhone, please visit https://support.apple.com/en-us/HT204505.
- **Note:** You can only onboard the feature from your iPhone.

When the Feature is Turned On

- The feature is turned on after on-boarding is complete. The feature runs in the background, receiving and analyzing data from your Apple Watch over the course of a 30-day window. You will receive a notification if the feature identifies possible hypertension based on the last 30-day window of data.
- You will not receive a notification if the feature did not identify possible hypertension over the course of a 30-day window.
- A new 30-day window starts automatically after the previous window ends.

- The feature requires at least 14 days of data collected while you are awake in each 30-day window to support data analysis. You will not receive a notification if the data collected is insufficient. It is recommended that you wear your Apple Watch consistently during the day for each 30-day window.
- New data cannot be collected once the storage on your Apple Watch is full. If necessary, you can free up space by deleting unwanted apps, music, or podcasts.

Receiving a Notification

- If you receive a notification, it is recommended that you take your blood pressure with an FDA-cleared blood pressure monitor for 7 days to provide valuable insights for you and your doctor. You should discuss the notification and any blood pressure measurements you record with your doctor at your next appointment.
- Your notification history is saved to the Health app on your iPhone or iPad. If you choose to, you can share that information by exporting your health data in the Health app.
- **NOTE:** The feature does not provide blood pressure measurements.

SAFETY AND PERFORMANCE

Clinical Validation Study

Apple conducted a large scale prospective clinical study to evaluate the performance of HTNF. A total of 2,229 subjects without a previous diagnosis of hypertension were enrolled in the clinical study. The subjects were enrolled from diverse demographic groups and representative of the intended use population with a range of blood pressures categorized as non-hypertensive (normal or elevated) or hypertensive (stage 1 and stage 2) in accordance with definitions published in the 2017 American Heart Association Guidelines[1]. All subjects were asked to wear an Apple Watch for 30 days and measured blood pressure using an FDA-cleared home blood pressure monitor as reference. Of the 2,229 enrolled subjects, 2,135 successfully completed the clinical study and 1,863 provided at least 15 days of usable data for the primary endpoint analysis.

[1] Whelton, P.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: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol, 2018. **71**(19): p. e127-e248

The clinical study results demonstrated that:

- The feature met all pre-determined primary endpoints. The overall sensitivity and specificity were 41.2%(95% CI [37.2-45.3]) and 92.3% (95% CI [90.6-93.7]), respectively.
- The sensitivity for stage 2 hypertension was 53.7% (95% CI [47.7-59.7]) and the specificity for normotensive was 95.3% (95% CI: [93.7-96.5]).
- Demographic subgroup analyses were conducted using covariate adjusted analysis to correct demographic imbalances. The results are presented as risk ratios in **Table 1** and **Figure 1,** where point estimates and confidence intervals of the ratio of sensitivities and ratio of specificities between categories of the demographic subgroups are reported. The demographic subgroup analyses were pre-specified and adjusted for age, sex, BMI, race, and blood pressure. For each evaluated demographic characteristic, the subcategory listed (or listed first, in **Table 1**) serves as the numerator of the risk ratio. For example, a sensitivity risk ratio of less than 1.0 in the younger age group (<60 years) means this group has a lower covariate-adjusted sensitivity than the older group (≥60) years. A specificity risk ratio of greater than 1.0 in the younger age group means this 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.

Table 1. Subgroup Performance Risk Ratio - HTNF Clinical Study

Subgroup		Sensitivity Risk Ratio [95% CI]	Specificity Risk Ratio [95% CI]
Age (<60 vs. ≥ 60)		0.69 [0.55, 0.85]	1.09 [1.04, 1.15]
Sex (Female vs. Male)		0.93 [0.77, 1.12]	0.97 [0.93, 1.03]
Race	**Not White vs. White**	0.87 [0.69, 1.10]	1.04 [1.01, 1.07]
	Not Black vs. Black	1.20 [0.93, 1.54]	0.97 [0.93, 1.00]
	Not Asian vs. Asian	1.42 [0.86, 2.35]	1.00 [0.97, 1.04]
Ethnicity (Hispanic vs. Not Hispanic)		1.41 [1.07, 1.88]	1.02 [0.97, 1.06]
BMI (≤ 30 vs. >30 kg/m$^{2)}$		0.67 [0.55, 0.81]	1.06 [1.02, 1.11]
Fitzpatrick Skin Tone (I-IV vs. V-VI)		1.11 [0.84, 1.47]	0.98 [0.93, 1.02]

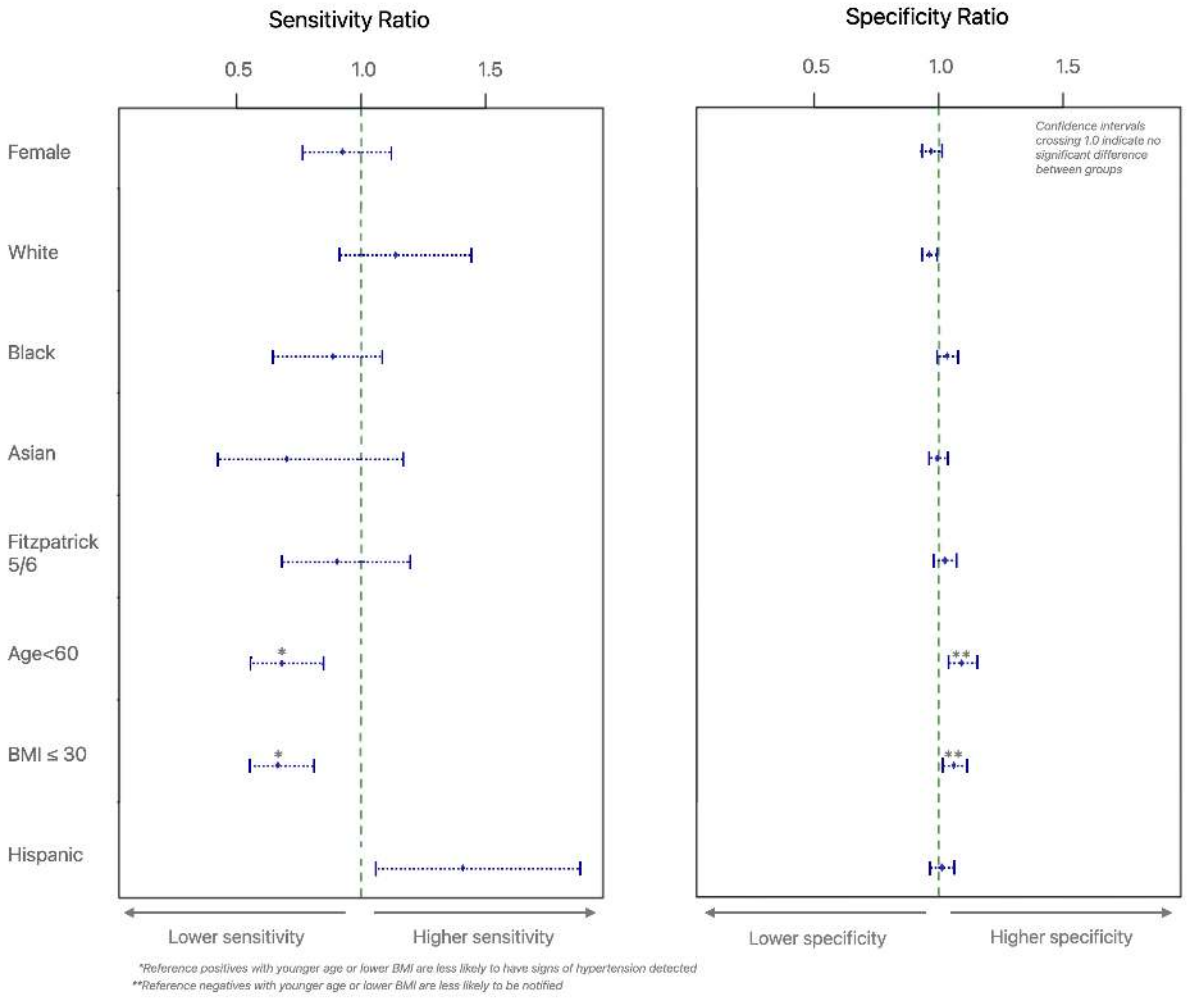

Figure 1: Subgroup performance Risk Ratio

- Higher sensitivity and lower specificity were observed in those with older age (age≥60 years) and higher BMI (BMI>30 kg/m^2). The result was deemed clinically acceptable due to the higher risk nature of these subgroups. 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 years) and had lower BMI (mean BMI 27.7 vs. 30.9 kg/m^2) compared to non-Asian participants. After covariate adjustment Asian performance characteristics were on par with non-Asian participants.

The clinical study was conducted with no protocol deviations that would have impacted the results. Finally, no serious device-related adverse events were reported in the study. Overall, the clinical study provides reasonable assurance of safety and effectiveness for the feature.

Longitudinal Performance Evaluation

A longitudinal study was conducted over two years to evaluate long-term performance of HTNF, analyzing patient data containing six discrete non-overlapping 30-day evaluation windows. After adjusting for demographic characteristic imbalances between this study and the pivotal clinical study to facilitate comparisons, the results showed the long-term specificity for non-hypertensives (N=187) remained high at 86.4% (95% CI [80.2%, 92.5%]), as did the specificity for the subset of non-hypertensives with normal blood pressure (N=121) which was 92.5% (95% CI [86.8%, 98.3%]). Importantly, as shown in **Figure 2**, the majority of participants with normal or elevated blood pressure who received a notification did so in the first month, and the number of new notifications within these groups tended to decrease month-over-month.

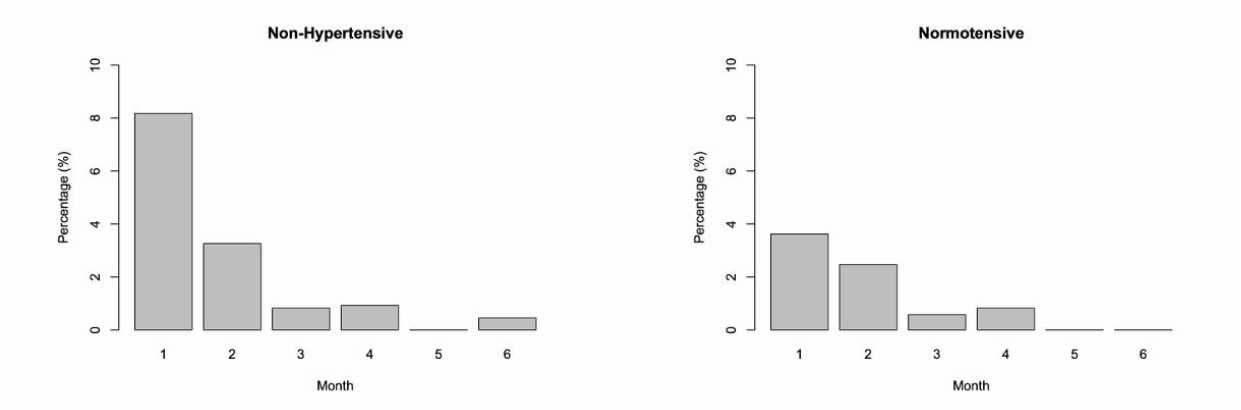

Figure 2 Adjusted Percentage of New False Positives Per Month Over 6 Months

HARDWARE SPECIFICATION

Device Requirement	• Apple Watch Series 9 or later, Ultra 2 or later, excluding Apple Watch SE • iPhone models compatible with iOS 26.0 or later

EQUIPMENT SYMBOLS

 Manufacturer

 Consult instructions for use

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099-44293 Revision C, September 2025, en_US