LEVERAGING APPLE WATCH

FOR CARDIOVASCULAR CARE

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FOR CLINICIANS

I. Document Summary

The purpose of these resources is to guide clinicians on the use of Apple Watch's regulated features in clinical practice should they choose to do so. These resources can also help clinicians advise their patients on how to optimize their experience with Apple Watch along their care journey. Apple Watch has multiple regulated features with marketing authorization from the U.S. Food and Drug Administration (FDA) and other regulators around the world. This guide focuses on Apple Watch's regulated features, including the ECG feature, Irregular Rhythm Notification (IRN) feature, and the Atrial Fibrillation (AFib) History feature (for users already diagnosed with AFib). Apple Watch has many other wellness features such as activity tracking, mindfulness experiences, sleep tracking, and cardiorespiratory fitness (VO2 Max).

II. Implementation Checklist

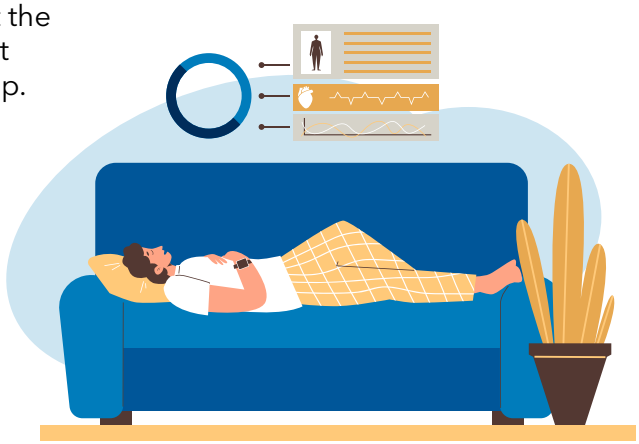
- ☑ Discuss sleep, activity tracking, and regulated heart health features with the patient.
- ☑ Discuss with the patient which arrhythmias and/or symptoms will be tracked.
- ☑ Assign and confirm the managing clinician who will receive to submitted electrocardiograms (ECG).
- ☑ Specify how long a patient may need to wait for a response to submitted ECGs.
- ☑ Reinforce the need to seek urgent medical attention for severe symptoms (e.g., syncope, near syncope).
- ☑ Make sure you have prepared links to online patient educational resources for Apple Watch use and data upload via EHR.
- ☑ Provide the patient with instructions on how to get started and list of frequently asked questions.
- ☑ Perform a "dry run" of an ECG transmission with the patient if they have an Apple Watch with them during their visit.

III. General Advice for Patients

Apple Watch is commonly used nowadays. As such, clinicians may increasingly be called upon to answer questions about its regulated health tracking features and to interpret its information. Some benefits of Apple Watch are that it is comfortable, user-friendly and can collect longitudinal data. Given its breadth of capabilities, it has the opportunity to provide wide-ranging insights on an individual's health and wellness.

Clinicians should first ensure that the regulated cardiac monitoring features are aligned with the patients' health goals, and that the information obtained is likely to inform patient management decisions. Clinicians can ensure that these features are set up. Patients should be advised of the following:

- Wear the watch snugly on their wrist.
- Be still when performing the ECG.
- Wear the watch as much as possible to take advantage of the Irregular Rhythm Notification (IRN) feature, the Atrial Fibrillation (AFib) History feature (for users already diagnosed with AFib) and the activity and sleep tracking features.



IV. Common Misperceptions About Arrhythmia Monitoring

Common misperceptions that patients may have about arrhythmia monitoring with Apple Watch include:

False

That all irregular rhythm notifications are AFib

- **TRUE:** Irregular Rhythm Notifications do not replace a diagnosis. While false positive rates are low, assessing each patient with a 12-lead ECG or clinician-prescribed ambulatory ECG monitor is important for a specific diagnosis of AFib. See Instructions for Use for additional information.

False

That all AFib events will be detected

- **TRUE:** Apple Watch is not always/continuously monitoring for AFib; the monitoring is performed opportunistically every two hours. The algorithm uses photoplethysmograph (PPG) based tachograms to identify an irregular rhythm and when it does, it then initiates a cascade of more frequent tachogram collection. If five or six tachograms in a 48-hour period are classified as irregular, the user will get a notification of a potential arrythmia. If two tachograms are classified as not irregular before the threshold is reached, the cycle is reset and the tachogram cadence goes back to every two hours.
- Apple Watch collects and analyzes tachograms only if the user remains still enough to obtain a reading.
- The clinical validation study showed that compared to a continuously monitoring ECG patch, the Irregular Rhythm Notification feature detected AFib with a sensitivity of 88%.

V. Key Technical Features of Apple Watch

The availability of the regulated features listed in this document depends on the Apple Watch model.

To determine the series of Apple Watch:

Open the Apple Watch app on the paired iPhone → My Watch (bottom left) → General → About → Look for Model Name.

More information can be found on the Apple Support page **here.**

Irregular Rhythm Notification

- Available for all Apple Watches Series 1 and later
  - Intended for use in patients 22 years of age and older
  - Not intended for use in patients previously diagnosed with AFib
  - Reference Instructions for Use for additional information
- Opportunistically analyzes pulse rate information to identify irregular heart rhythms that may be AFib. *Note that this is not continuous monitoring*.

Ability of Apple Watch to identify irregular rhythms may be impacted by wrist tattoos and environmental conditions like temperature.

Note that not every irregular rhythm is necessarily identified, and the absence of notification does not mean an irregular rhythm is not present.

Onboarding Process

Health app → **Browse** → **Heart** → **Irregular Rhythm Notifications**

(ensure AFib History is not enabled)

If a notification is triggered, data in Health app can be exported to be shared with clinicians. More information regarding best way to do this in the patient-facing documents.

For more information, refer to the Apple Support page **here.**

ECG

- Available for all Apple Watches Series 4 and later, excluding Apple Watch SE
  - Intended for use in patients 22 years of age and older
  - Instructions on how to use ECG can be found here
- Generates, records, stores, and enables sharing of a single-channel ECG similar to lead I on a 12 lead
  - Classifications:
    - Sinus rhythm
    - Atrial Fibrillation (classifiable between 50-120 bpm for version 1 and 50-150 bpm for version 2)
    - Low or high heart rate (HR outside of classifiable range)
    - Inconclusive
    - Poor recording (version 2 only)
  - Note inconclusive is a potential outcome on both version 1 and version 2
- Patients can try to obtain ECGs for their non-urgent symptoms.

Onboarding Process

Health app → **Browse** → **Heart** → **ECG**

Recording ECG with Apple Watch must be snug on the wrist

1. Open ECG application on Apple Watch → **2. Rest arms on table or lap** → **3. Hold finger on digital crown and wait 30 seconds**

- ECG data can be exported to be shared with clinicians
  - Please refer to Section 2 for patient education materials that include instructions on how to record an ECG and how to export a PDF to send to their clinician
- If patients get an "inconclusive" reading, they should follow the steps in the "troubleshooting checklist". Consider asking patient to obtain a repeat tracing in case artifact is playing a role, and sending both for comparison/evaluation
- If they continue to get "inconclusive" readings, they should still capture ECGs and send PDFs since these "inconclusive" readings can contain relevant information and should be reviewed by clinicians (e.g., premature atrial or ventricular contractions)
- More information can be found on the Apple Support page here

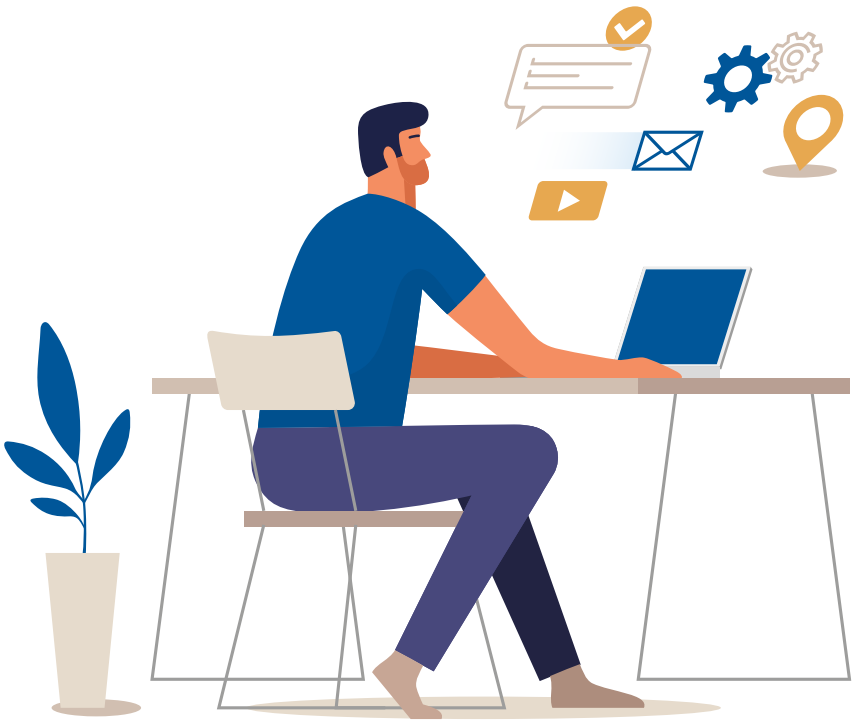
Irregular Rhythm Notification Feature PPG-based detection	ECG Feature ECG-based detection
- Uses green LED lights paired with light-sensitive photodiodes to detect blood volume pulses in user's wrist - Arrhythmia detection feature needs to be enabled to capture tachograms - Irregular tachograph would initiate more frequent tachogram cycle for confirmation process	- The electrode on the digital crown of Apple Watch and on the back crystal of Apple Watch allows the ECG app to read and record electrical impulses from the heart via user's fingertip (on Digital Crown) and wrist - ECG app needs to be opened for ECG to be recorded, which then classifies the ECG - ECG tracing can be classified as sinus rhythm, AFib or inconclusive. ECG 2.0 has additional classifications as noted above

AFib History Feature

- Available for Apple Watch Series 4 or later
  - Intended for use in patients 22 years of age and older who have a known diagnosis of AFib
  - Instructions on how to use AFib History can be found here
- Estimates AFib burden during Apple Watch wear time over the prior 7 days
  - Shows the potential impact of exercise, sleep, weight, alcohol consumption and mindful minutes (exercise, sleep, mindful minutes logged automatically)
  - After 6 weeks, AFib History highlights will be developed across 4-hour segments of the day
  - Requires Apple Watch wear at least 5 days per week for 12 hours per day, which allows for collection of at least 70 tachograms

Onboarding Process

Health app → **Browse** → **Heart** → **AFib History**



Learn more about collecting and managing long-term data through Apple Watch, please refer to the Apple Support page **here**.

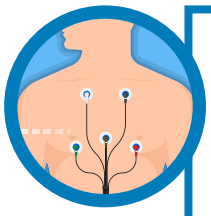
Learn more about using the Health app **here**.

VI: Best Practices

Apple Watch is best used for general health and wellness, pre-clinical scenarios, or in certain clinical situations in which an arrhythmia has already been identified and is being appropriately managed (e.g., assessment of AFib burden). In situations in which real-time notification of data to clinicians and patients is necessary, a continuous ECG monitor is strongly advised.

When NOT to use Apple Watch (e.g., not recommended for clinically indicated rhythm monitoring). Devices that continuously monitor and provide immediate alerts are better suited for the evaluation and management of:

- Suspected cardiogenic syncope
- Evaluation of AFib/flutter after cerebrovascular accident or systemic embolism
- Characterizing arrhythmias other than AFib (such as supraventricular tachycardias, ventricular tachycardia, suspected tachycardia, or bradyarrhythmias)
- Monitoring for arrhythmias when clinical decisions (such as prescribing anticoagulation) are contingent upon the findings



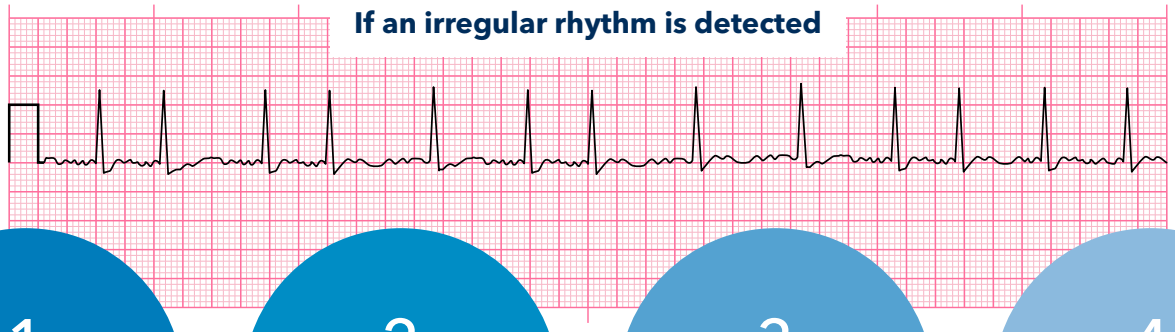
There are many devices used for conventional rhythm monitoring that continuously monitor and can provide immediate alerts, which include:

- 24-48 hour Holter monitors (continuous ECG monitoring, usually with multiple leads)
- 30-day event monitors (on-demand ECG monitors that patients apply at time of event)
- 14-28 day patch-based ECG monitors (single-lead ECG monitors that provide continuous monitoring, usually with data on heart rate trends, arrhythmia burden, and patient symptom correlation)
- Implantable loop recorders (single-lead ECG monitors that can last 2-6 years with continuous monitoring and alert reporting)

Situations in which Apple Watch can be useful:

- Detect a clinically relevant arrhythmia via Irregular Rhythm Notification (IRN) feature or ECG app, with high sensitivity to detect AFib. For those with known AFib, estimate the percentage of time in AFib.
  - Please refer to the Apple Support pages below for more information:
    - IRN
    - ECG
    - AFib History
- Monitor heart rates, with the ability to set notifications for low and high heart rates that can be used to:
  - Monitor for bradycardia or tachycardia with correlation to any symptoms
  - Assess heart rate response to exercise and recovery

More information about using Apple Watch for arrhythmia detection can be found on the white paper **here**.



1 Confirmation

Apple Watch is sensitive to AFib and irregular rhythms, but clinical confirmation is needed. This can be done using:

a. 12-lead ECG, if the patient is suspected to still be in the rhythm

b. Devices that continuously monitor and provide immediate alerts, such as 48-hour Holter or patch-based rhythm monitor, if the rhythm is paroxysmal.

2 Evaluation

Upon confirmation of the rhythm abnormality, clinical evaluation and guideline-directed testing should be followed. This may include laboratory evaluation (e.g., renal function, electrolyte abnormalities, thyroid stimulating hormone), cardiac testing (e.g., echocardiogram) or referral to cardiology or cardiac electro-physiologists as indicated.

3 Treatment

For a diagnosis of AFib, anticoagulation therapy may be indicated to prevent stroke and systemic embolism. Other considerations may be medications to control ventricular rates or reduce risk of recurrent AFib, or a referral to electrophysiology for consideration of catheter ablation. For AFib, the cardiac multi-society clinical guideline provides management recommendations here.

4 Follow-Up

Continue patient management; if an AFib diagnosis is confirmed, AFib History feature can be used to help identify lifestyle correlations.

VII: Apple Watch Workflow for Clinicians

Before clinical encounters, consider familiarizing yourself with key technical features (Section V) and best practices (Section VI).

During clinical encounters, consider following these steps to guide your patient in the optimal use of the Apple Watch.

1

Set clear expectations:
For each patient, make clear the types of scenarios/symptoms that warrant sending in an ECG. These instructions will be different for each patient. Also be sure to set expectations for how quickly the patient can expect a response from you via the patient portal. The patient must understand that if they are experiencing an emergency, they need to seek immediate medical attention by calling 911 -- even if they are recording ECGs and they have not yet heard from their clinical care team.

2

Provide guidance on types of rhythm that patients should send:
Given the clinical scenario with a particular patient, consider providing guidance on what type of information from Apple Watch should be transmitted via the EHR (e.g., palpitations with inconclusive readings that may capture PVCs; patient with history of AFib should send percentage of time in AFib).

3

Refer patients to the appropriate educational materials:
Make sure your patients receive the appropriate educational forms for Apple Watch, which may include: "How to Use Apple Watch to Record ECGs and Send them to my Clinical Care Team" and "Frequently Asked Questions". These forms could be distributed to patients through an EHR-based communication (e.g., the after-visit summary in Epic - consider making a Smartphrase/dot-phrase that can be quickly added to save you time) or as a written letter or secure attachment.

4

Explain to the patient that in using EHR-based communications, they must specify the clinician to whom the PDF files of the ECG readings will be sent to:
Make sure that you agree in advance who should be the appropriate recipient/team of the PDF files. Depending on the patient and the practice, the recipient/team could be either the managing physician or broader team. The patient needs to know that delivery to an inappropriate recipient will delay care.

5

If the patient has their Apple Watch on during a clinical encounter, consider having them send a "practice" ECG to the clinician via the patient portal:
Patients should attach PDF files of ECGs to EHR inbox messages addressed to their clinical care team (this could be their treating physician or an associated advanced practice professional, based on the preference of clinician and patient). This could be a good opportunity to provide real-time troubleshooting.

6

Be consistent regarding the viewing/interpretation of ECGs sent by patients:
If the ECGs are sent as PDFs attached to EHR inbox images, the clinician should receive an automated alert in their inbox (please verify EHR settings to ensure appropriate notifications are turned on). The clinician will be able to open the alert message, view the ECG, record their interpretation, and communicate the findings to the patient. Example communication methods are included below.

a. The clinician could write a portal message to the patient that will be recorded as a note in the chart (this is preferred as it preserves the link to the tracing for future viewing).
b. The clinician could call the patient and leave a phone note.
c. The clinician could leave a written note for the patient.

VIII: Tools for Clinicians to Use With Their Patients

Consider using the patient handouts included in the following section with your patients. The content can be distributed by the clinical care team to patients (could be pasted into the after-visit summary or similar patient instructions/handout in the EHR, other EHR-based communications, or even printed letters).

FOR PATIENTS

What's Inside:

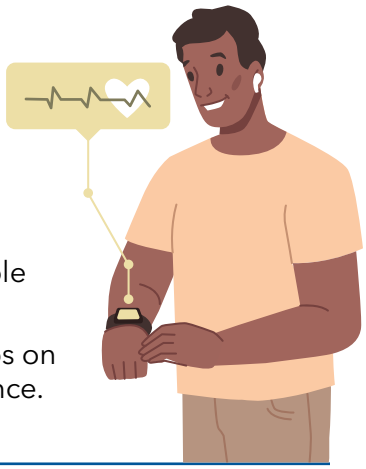
1. What Role Can Apple Watch Play in Helping Monitor My Heart Health?

Your Apple Watch can help you identify if you may have a heart rhythm problem (called an arrhythmia) using the Irregular Rhythm Notification Feature (see Appendix). Once you set the feature up, it operates in the background and does not require any action from you. If you experience symptoms, such as a skipped heartbeat, you can also record an electrocardiogram (ECG) to share with your health care provider. If you are already diagnosed with atrial fibrillation (AFib), you can view past records to track how frequently your heart is in AFib with the AFib History Feature.

2. How to Use Apple Watch to Record ECGs and Send Them to My Clinical Care Team

Any Apple Watch (Series 4 or later, excluding Apple Watch SE) can be used to record an ECG – a test with sensors that can record your heart's electrical activity. Recording and sending these ECGs to your clinical care team can be a convenient way to track your heart rhythm and help inform conversations about your heart health with your care team.

ECG and IRN cannot detect heart attacks. AFib History cannot detect heart attacks and should not be relied on as a continuous monitor. AFib History is not intended to be used to aid in the medical management of AFib. Users with a history of non-AFib irregular heart rhythms may have higher than expected AFib burden estimate.

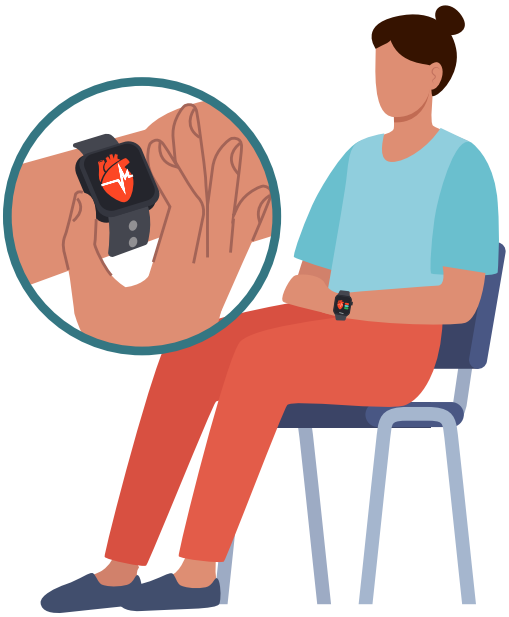


Step 1: Set up my Apple Watch and find the ECG app

Open the Health app, go to the Browse tab and then tap Heart. Scroll to ECG and complete the onboarding process. Additional information can be found on the Apple Support article here.

This article will show you how to use the ECG app on your Apple Watch. It also has tips on how to get more accurate readings and how to deal with any issues you may experience.

Step 2: Record an ECG using my Apple Watch



1. Make sure your Apple Watch fits snugly on top of your wrist.
2. Open the ECG app.
3. Rest your arms on a table or on your lap.
4. With the hand opposite to that with your watch, hold your finger on the crown of the watch. For best results, do not push on the crown or move the watch on your wrist.
5. Stay still and wait 30 seconds to allow the recording to complete.
6. Once the recording is finished, you will receive one of the few possible results: Sinus Rhythm (regular heart pattern), Atrial Fibrillation (irregular rhythm), Low Heart Rate, High Heart Rate, Inconclusive or Poor Recording. You will have the opportunity to make note of any symptoms by tapping "Add Symptoms."

Step 3: Send the recorded ECGs to my clinical care team

1. Open the Health app and go to the Browse tab then tap Heart. Scroll to and tap ECG. Select the ECG you want to share.
2. Tap Export PDF and then tap the share button in the top right corner. Then, select Save to Files and choose the desired location on your phone. Saving and sharing the report in this way is recommended as it provides your care team with more information than only sharing a screenshot of the rhythm strip.
3. Log in to the patient portal on your smartphone (please use the address for the web-based patient portal provided by your clinical care team).
4. Select your clinical care team member to send a message in the usual manner.
5. Tap the attachment symbol at the bottom of the screen. This will allow you to select the ECG file from the folder in which it was saved. Select your file and send your message.

3. Frequently Asked Questions About Recording ECGs With Apple Watch

How do I handle ECGs labeled by the app as "Inconclusive"?

Do not delete these recordings. Send them to your clinical care team, as they may contain valuable information.

How do I handle ECGs labeled by the app as "Poor Recording"?

Do troubleshoot your recording process (see "How do I troubleshoot a poor recording?" below) and then perform another recording to also send to your clinical care team.

How do I troubleshoot a Poor Recording?

Follow these steps and record another ECG:

1. Adjust the wristband of your Apple Watch so that it sits snugly on your wrist.
2. Place your arms in a resting position (in your lap or on a flat surface, like a table).
3. When you touch the crown of your watch to initiate the recording, do not push on the crown or push the watch up your wrist.
4. Remain still and don't talk during the recording.
5. If these steps do not help, please refer to Apple's troubleshooting guide: **https://support.apple.com/en-us/HT208955**

Can I share a screenshot of an ECG from my phone with my care team?

It's best to send PDF files of ECGs from your Apple Watch whenever possible. Screenshots can be sent if there is no alternative, but the quality of screenshots is often poor. Bad image quality may limit your clinical care team's ability to interpret the ECG. In addition, screenshots do not contain a time stamp the way a Health app-prepared PDF file does. Without a time stamp, you and your care team will have a harder time matching the ECG reading and reported symptoms.

Why is symptom reporting important?

Reporting symptoms is important because it allows your clinical care team to accurately access your condition and make informed decisions. Some arrhythmias can cause a sudden drop in your blood pressure and lead to symptoms such as profound lightheadedness, near loss of consciousness, or loss of consciousness. If you experience any such symptoms, please seek urgent medical attention. For less concerning symptoms such as short-lived lightheadedness, palpitations, or a sensation of your heart racing, you can generally use your Apple Watch to record your heart rhythm during these symptoms and reach out to your clinical care team for advice about whether the rhythm may be responsible.

If I send my clinical care team an ECG through the patient portal, how soon should I expect to receive a response?

Please ask your clinical care team how quickly they will reply through the electronic health record (EHR) inbox. If you are experiencing serious symptoms such as lightheadedness, near loss of consciousness, or loss of consciousness, please seek urgent care (and call 911 if appropriate) even if you have not heard back from your clinical care team yet.

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Author Disclosures

Dr. O'Quinn is a consultant for AstraZeneca Pharmaceuticals, Belgium Hemataology Society, BRACCO Diagnostics, and Zoll. Dr. Desai is a consultant for Bayer Healthcare Pharmaceuticals and Merck & Co., Inc. Dr. Dhruva reports equity in Apple and Google; is a member of the Institute for Clinical and Economic Review California Technology Assessment Forum; and is a member of the Medicare Evidence Development and Coverage Advisory Committee. Dr. Ptaszek is a consultant for St. Jude Medical, Anumana, Bristol Myers Squibb, Medtronic, Moderna, and Voiant. Dr. Pundi is a consultant for Evidently and iRhythm.

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Appendix: Resources

Feature Validation Paper

- Using Apple Watch for Arrhythmia Detection

Apple Support Pages

- Determine Apple Watch Model
- Enable Heart Rate and Irregular Rhythm Notifications
- Record an ECG with the ECG App
- Track AFib History
- Manage Your Health Data
- Setting Up and Using the Health App

Instructions for Use

- Irregular Rhythm Notification 1.0
- Irregular Rhythm Notification 2.0
- ECG 2.0
- AFib History

CardioSmart Resources

- Heart Rhythm Problems (topic hub)
- Heart Rhythm Problems: Record Your Symptoms (worksheet)
- Common Questions About Abnormal Heart Rhythms (handout)
- Heart Rhythm Problems: How Heart Monitors Work (infographic)
- Could I Have a Problem With My Heart Rhythm? (handout)