



Expanded use of Apple ECG app for supporting remote heart rhythm evaluation during the COVID-19 pandemic

This document provides an overview of how the ECG app on Apple Watch Series 4 or later can be used in telemedicine and remote monitoring during this time of public health crisis.

The FDA recently published guidance expanding the use of certain noninvasive patient-monitoring technologies, including the ECG app, during the coronavirus disease 2019 (COVID-19) public health emergency.¹ This expanded use is intended to help facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID-19.

With this FDA guidance, healthcare providers can now access, for the duration of the pandemic, the expanded capability of the ECG app on Apple Watch for telemedicine services. To support providers as they remotely measure and record ECG, this document outlines the ECG app expanded capability, including typical use cases and additional details on how to successfully use the ECG app as part of telemedicine.



How to use the ECG app

During the COVID-19 national emergency in the U.S., the ECG app on Apple Watch can serve as a substitute for in-clinic diagnostic testing. Healthcare providers can use it for clinical use cases where a single-Lead or Lead I ECG test can help effectively diagnose certain arrhythmias or manage related conditions.

The ECG app is not intended to be used for triaging emergency clinical situations, such as a suspected heart attack, respiratory distress, or other severe clinical conditions that require immediate attention. Also, healthcare professionals and patients shouldn't rely solely on the app to make clinical diagnoses or treatment decisions.

Here's a typical workflow between a provider and patient:

- ① The healthcare provider identifies a telemedicine visit—by video, telephone, or asynchronous email—in which the use of single-Lead ECG is appropriate. The provider requests that the patient take an ECG recording through the ECG app on Apple Watch before or during a virtual consultation.
- ② The patient records an ECG through the ECG app. After a successful ECG recording, the patient has the option to input symptoms associated with the recording. Next, the patient exports a PDF that contains the waveform recording, the classification, and any symptoms the patient entered. For details on how to use the ECG app, see the Apple support web page at support.apple.com/en-us/HT208955.
- ③ The patient shares this PDF with the provider through secure messaging based on the provider's EMR and IT systems. The provider reviews the ECG recording waveform and other clinically relevant information to make a diagnosis, as well as recommendations for further diagnostic testing if needed. The doctor can do this without requiring that the patient physically visit the office.

If a clinician uses Epic EMR, a patient can share a PDF of the ECG in a message in MyChart, which automatically attaches it to the patient's chart in Epic. When the patient sends the PDF through MyChart, it will appear in the provider's In Basket so the provider can view it—as well as in other areas in Epic—without user intervention. If you find that patients aren't able to attach PDFs to MyChart messages, reach out to your organization's Epic team to enable this functionality.

- ④ The ECG app, in this use case, is intended only for supporting diagnoses in the setting of a patient-and-provider interaction. Only a qualified provider should make a final interpretation and diagnosis of rhythms based on the ECG recording through the ECG app.

Similarity of the ECG app waveform to Lead I and performance of AFib classification

In 2018, Apple sponsored a two-part, multicenter study to validate the ability of the ECG app to:

- Generate an ECG waveform similar to a Lead I ECG from a standard 12-Lead ECG
- Classify heart rhythms as either sinus rhythm or atrial fibrillation (AFib)²

The ECG app classification algorithm achieved a 98.3 percent sensitivity and 99.6 percent specificity in distinguishing AFib. For the diagnosis of other significant arrhythmias, the ECG app also demonstrated high concordance in its generated waveform overlay compared with Lead I on the 12-Lead reference Lead. This means that a provider can interpret the waveform generated by the ECG app as similar to a Lead I waveform from an in-office 12-Lead ECG.

ECG data protection and privacy

Apple Watch health features—including the ECG app—were designed to protect user privacy. All health data, such as the ECG recording in the Health app on iPhone, is stored encrypted on the user's device. If a user chooses to sync their health data with iCloud, it's encrypted while in transit and at rest. No data is shared without a user's permission.

Clinical use cases

Examples of use cases for the ECG app during the COVID-19 pandemic include:

- Telemedicine visits in which a Lead I ECG waveform is needed as part of standard care
- Virtual care in which a Lead I ECG waveform is needed as part of standard care

For more information on use cases for remote monitoring technologies during the COVID-19 pandemic, see recent AHA and ACC guidelines at [heartrhythmjournal.com/article/S1547-5271\(20\)30552-X/fulltext](https://www.heartrhythmjournal.com/article/S1547-5271(20)30552-X/fulltext).

Limitations of the ECG app

The ECG app isn't designed to help triage urgent conditions, such as myocardial infarction or pericarditis. The classification algorithm for the ECG app has been evaluated only for detection of AFib or normal sinus rhythm and isn't intended to detect any other type of arrhythmia. The ECG app in this indication shouldn't be used to assess conditions that require ECG Lead waveforms other than Lead I.

Conclusion

With the new FDA guidance, healthcare providers can access the expanded capability of noninvasive remote monitoring devices during the COVID-19 pandemic. As outlined in this paper, providers can now use Apple Watch and the ECG app for telemedicine and virtual care, helping facilitate both patient care and social distancing to minimize potential exposure to COVID-19.

References

- “Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff,” Food and Drug Administration, March 2020, [fda.gov/media/136290/download](https://www.fda.gov/media/136290/download).
- The ECG app was originally permitted marketing on September 11, 2018, for the following indications for use:

The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.

The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

“ECG - FDA” (ECG app marketing authorization letter), Food and Drug Administration, September 11, 2018, accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf.

- “De Novo Classification Request for ECG App,” Food and Drug Administration, 2018, accessdata.fda.gov/cdrh_docs/reviews/DEN180044.pdf.

1. Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency, March 2020. [fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during)

2. For detailed results of the ECG app's performance, see apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf.