

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
WACO DIVISION**

ALIVECOR, INC.,

Plaintiff

v.

APPLE, INC.,

Defendant

Civil Action No.: 6:20-cv-1112

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AliveCor, Inc. (“AliveCor” or “Plaintiff”) for its Complaint for Patent infringement (“Complaint”) against Apple Inc. (“Apple” or “Defendant”), hereby alleges as follows:

THE PARTIES

1. Plaintiff AliveCor, Inc. is a Delaware corporation having its principal place of business at 444 Castro St, Suite 600, Mountain View, CA 94041.
2. AliveCor is the owner by assignment of U.S. Patent No. 10,595,731 (“the ’731 Patent”) (attached as Exhibit 1), U.S. Patent No. 10,638,941 (“the ’941 Patent”) (attached as Exhibit 2), and U.S. Patent No. 9,572,499 (“the ’499 Patent”) (attached as Exhibit 3) (collectively, the “Patents-in-Suit”).
3. Defendant Apple Inc. is a California corporation with a principal place of business at One Apple Park Way, Cupertino, California 95014. Apple can be served through its registered agent, CT Corporation System, 818 W. Seventh Street, Suite 930, Los Angeles, California, 90017.
4. Apple is registered to do business in Texas.
5. Apple has regular and established places of business in this District, including, at 3121 Palm Way, Austin, Texas, 2901 S. Capital of Texas Hwy., Austin, TX, and 12535 Riata Vista Circle, Austin, Texas, and 5501 West Parmer Lane, Austin, Texas. Apple employs thousands of

people, including hundreds of engineers, logistics managers, and other employees who work at these locations in Texas. The work done at these Apple locations in Texas includes work related to the Apple Watch.

6. The Apple Watch Planning Manager and the Americas Supply and Demand Planner work in Austin, Texas. These Apple employees likely have relevant information relating to, for example, product planning, marketing, historical sales, and forecasted sales of the infringing products.

7. Apple's Digital Strategy Program Manager is also located in Austin, Texas. According to the Digital Strategy Program Manager's LinkedIn profile, Apple created and managed the introduction of the Apple Watch ECG application, which is the accused technology in this litigation, in Austin. Apple's Digital Strategy Program Manager likely has information relevant to Apple's infringement and the amount of damages due.

8. Doctors at the Dell Medical School at the University of Texas at Austin as well as the Ascension Seton Medical Center in Austin, Texas also performed a first of its kind study of the infringing Apple products and features. These doctors performed a study to confirm the accuracy of the accused Apple products and features, and validate the use of the accused Apple watch for patients and health care providers. The results of the study were published in a paper entitled "A comparison of manual electrocardiographic interval and waveform analysis in lead 1 of 12-lead ECG and Apple Watch ECG: A validation study." (Attached as Exhibit 4). As described by the doctors who conducted the study, the Apple Watch Series 4 (AW) "contains built-in software and hardware to perform a single-lead electrocardiogram (ECG) and detect atrial fibrillation." Ex. 4 at 30. The goal of the study was to "compare the accuracy and correlation of the intervals and waveforms derived from the single-lead AW ECG with lead 1 of a standard 12-lead ECG by performing manual interval measurements and waveform analysis in a healthy adult population." *Id.* The study's participants, all of whom used the infringing devices during the investigation, were also located in and around Austin, Texas. *Id.* at 31. Finally, the doctors who performed the study—

all of whom appear to be located in Austin, Texas—have relevant, discoverable information regarding infringement, validity, and damages. *Id.* at 30.

9. Apple has hired or is hiring engineers to join Apple’s Austin-based Custom Silicon Management Group. The Austin-based Custom Silicon Management Group will likely have unique information relevant to infringement including but not limited to information regarding product design, the relevant functionality, and product performance.

10. Apple also has a physical place of business in the Western District of Texas including Apple Stores at Barton Creek Square, Austin, Texas and at Apple Domain Northside, Austin, Texas. Apple uses, offers for sale and sells series 4 and later version of Apple’s Watch with the ECG Application installed.

11. Apple has placed or contributed to placing infringing products like the Apple Watch into the stream of commerce via an established distribution channel knowing or understanding that such products would be sold and used in the United States, including in the Western District of Texas. On information and belief, Apple also has derived substantial revenues from infringing acts in the Western District of Texas, including from the sale and use of infringing products like the Apple Watch.

JURISDICTION AND VENUE

12. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has specific personal jurisdiction over Defendant at least in part because Defendant conducts business in this Judicial District. AliveCor’s causes of action arise, at least in part, from Defendant’s contacts with and activities in the State of Texas and this Judicial District. Upon information and belief, Defendant has committed acts of infringement within the State of Texas and this Judicial District by, *inter alia*, directly and/or indirectly using, selling, offering to sell, or importing products that infringe one or more claims of the ’731 Patent, the ’941 Patent, and/or the ’499 Patent.

14. Defendant has committed acts within this District giving rise to this action and has established sufficient minimum contacts with the State of Texas such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), (c), and 1400(d) because (1) Defendant has done and continues to do business in this Judicial District, (2) Defendant has a regular and established place of business in this Judicial District, and (3) Defendant has committed and continues to commit acts of patent infringement in this Judicial District by, *inter alia*, directly and/or indirectly using, selling, offering to sell, or importing products that infringe one or more claims of the '731 Patent, the '941 Patent, and/or the '499 Patent.

ASSERTED PATENTS

16. AliveCor is the owner, by assignment, of U.S. Patent No. 10,595,731, titled “Methods and systems for arrhythmia tracking and scoring.” A true and correct copy of U.S. Patent No. 10,595,731 granted by the U.S. Patent & Trademark Office is attached as Exhibit 1.

17. AliveCor is the owner, by assignment, of U.S. Patent No. 10,638,941, titled “Discordance monitoring.” A true and correct copy of U.S. Patent No. 10,638,941 granted by the U.S. Patent & Trademark Office is attached as Exhibit 2.

18. AliveCor is the owner, by assignment, of U.S. Patent No. 9,572,499, titled “Methods and systems for arrhythmia tracking and scoring.” A true and correct copy of U.S. Patent No. 9,572,499 granted by the U.S. Patent & Trademark Office is attached as Exhibit 3.

BACKGROUND

19. Cardiovascular diseases are the leading cause of death in the world. In the United States, heart disease is the leading cause of death for men, women, and people of most racial and ethnic groups. <https://www.cdc.gov/heartdisease/facts.htm>. One person dies every 36 seconds in the United States from cardiovascular disease. *Id.* About 655,00 Americans die from heart disease each year. *Id.*

20. Arrhythmia is a cardiac condition in which the electric activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal. '499 Patent at 1:31-33.

Arrhythmias can cause cardiac arrest and even sudden cardiac death. *Id.* at 1:33-35. Atrial fibrillation is the most common cardiac arrhythmia. *Id.* at 1:35-36. In atrial fibrillation, electrical conduction through the ventricles of the heart is irregular and disorganized. *Id.* at 1:36-38. Atrial fibrillation symptoms include palpitations, shortness of breath, fainting, chest pain, or congestive heart failure. *Id.* at 1:38-40. Atrial fibrillation is also associated with atrial clot formation. *Id.* at 1:40-42. In some cases, after a clot forms it can migrate causing, among other things, stroke. *Id.*

21. Arrhythmias may occur continuously or may occur intermittently. '941 Patent at 1:34-35. Continuous arrhythmias are always present or almost always present. *Id.* at 1:40-43. Thus, they can be easily diagnosed with well-known diagnosis equipment and techniques. *Id.* For intermittent arrhythmias, however, the normal diagnosis equipment and techniques only work if the arrhythmia occurs during the diagnostic procedure. *Id.* at 1:43-49.

22. Unlike continuous arrhythmias, diagnosing intermittent arrhythmias is difficult, because, for example, it is not practical to be prepared to apply known diagnostic equipment and techniques at the exact time that an individual experiences an intermittent arrhythmia. *Id.* at 49-53. This particular difficulty may be compounded when an individual is not aware that they are experiencing an intermittent arrhythmia so that they would not, for example, seek out a health care provider during the intermittent arrhythmia. *Id.* at 1:53:57. The inventors of the '731, the '941, and the '499 Patents were thus presented with a technical problem: how to provide an arrhythmia diagnosis when the known diagnostic equipment and techniques were unavailable and/or unfeasible. '941 Patent at 1:26-3:26; '499 Patent at 1:20-2:4.

23. The claims of the '731, the '941, and the '499 Patents are novel, unconventional and focus on specific means and methods of using specialized sensors in a wearable device to improve upon existing cardiac monitoring technology. The Patents-in-Suit explain the state of the art in arrhythmia diagnosis, the limitations in known diagnostic techniques and diagnostic equipment, and the need for the inventors' improvement in diagnostic techniques and equipment. '941 Patent at 1:26-3:26; '499 Patent at 1:20-2:4. The claims then recite specific and novel implementations of apparatus and methods used for diagnosing intermittent arrhythmias that address the limitations in

the prior art including the requirement that the users be aware of the potential arrhythmia and have ready access to specialized diagnostic equipment in a clinical setting. In the Patents-in-Suit, a unique and novel combination of sensors are used to sense certain parameter values such as, for example, heart rate and activity level, which are then analyzed to predict or determine the presence of an arrhythmia. *See, e.g.*, '731 Patent at 26:27-52. These novel wearable devices differ from the disclosed and known prior art for several reasons including the incorporation and coordinated use of photoplethysmography ("PPG"), electrocardiography ("ECG"), and movement sensors in order to collect accurate, real-time cardiac data of the user and compare such data to the expected cardiac data based on the activity level of the user. *Id.* at 4:46-5:29. The claimed invention thus offers a uniquely convenient heart monitoring apparatus and method that leverages wearability, specialized sensors, and machine learning to generate more accessible and effective diagnosis of potentially dangerous arrhythmia conditions.

COUNT I

Apple's Infringement of U.S. Patent No 10,595,731

24. AliveCor restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

25. AliveCor is the owner, by assignment, of U.S. Patent No. 10,595,731, titled "Methods and systems for arrhythmia tracking and scoring." A true and correct copy of U.S. Patent No. 10,595,731 granted by the U.S. Patent & Trademark Office is attached as Exhibit 1.

26. Defendant Apple has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '731 Patent by making, using, selling, and/or offering for sale its Apple Watch Series 4 and later devices with the ECG App ("Apple Accused Products") in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.*, <https://support.apple.com/guide/watch/ecg-apdea4c50a57/7.0/watchos/7.0>. Apple has also infringed, and is continuing to infringe, literally or under the doctrine of equivalents claims 2, 12, and 13 of the '731 Patent.

27. At least as of the filing of the complaint, Defendant Apple has knowledge of the '731 Patent.

28. As a non-limiting example, the Apple Watch Series 5 is a smart watch to detect the presence of an arrhythmia of a user as required by claim 1 of the '731 Patent. As a way of illustration, the Apple Watch Series 5 is a smart watch that can detect the presence of an arrhythmia. According to the Apple website,

“Your finger can tell you a lot about your heart. Electrodes built into the Digital Crown and the back crystal work together with the ECG app to read your heart’s electrical signals. Simply touch the Digital Crown to generate an ECG waveform in just 30 seconds. The ECG app can indicate whether your heart rhythm shows signs of atrial fibrillation — a serious form of irregular heart rhythm — or sinus rhythm, which means your heart is beating in a normal pattern.”

<https://www.apple.com/apple-watch-series-5/>.



<https://www.apple.com/healthcare/apple-watch/>.

29. The Apple Watch Series 5 includes a processing device, i.e. a 64-bit dual-core S5 processor.

Series 5



64-bit dual-core S5 processor
Up to 2x faster than S3 processor

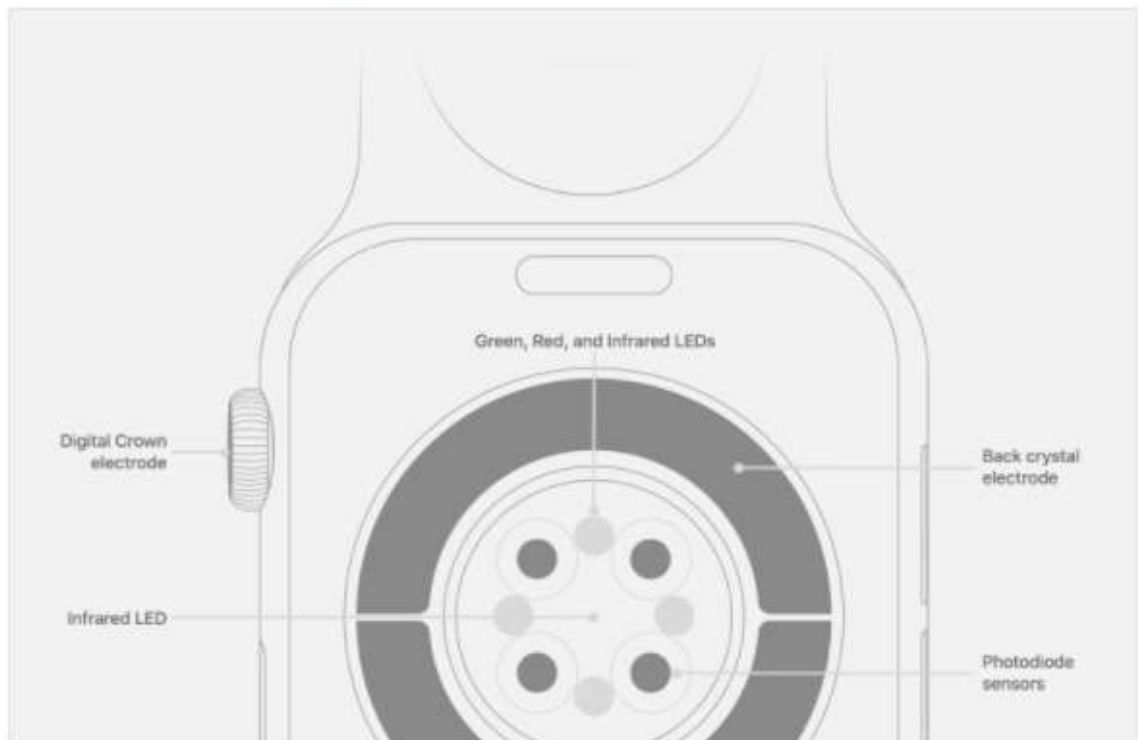
[https://www.apple.com/watch/compare/.](https://www.apple.com/watch/compare/)

30. The Apple Watch Series 5 includes a PPG sensor operatively coupled to the processing device.

How Apple Watch measures your heart rate

The optical heart sensor in Apple Watch uses what is known as photoplethysmography. This technology, while difficult to pronounce, is based on a very simple fact: Blood is red because it reflects red light and absorbs green light. Apple Watch uses green LED lights paired with light-sensitive photodiodes to detect the amount of blood flowing through your wrist at any given moment. When your heart beats, the blood flow in your wrist — and the green light absorption — is greater. Between beats, it's less. By flashing its LED lights hundreds of times per second, Apple Watch can calculate the number of times the heart beats each minute — your heart rate. The optical heart sensor supports a range of 30–210 beats per minute. In addition, the optical heart sensor is designed to compensate for low signal levels by increasing both LED brightness and sampling rate.

The optical heart sensor can also use infrared light. This mode is what Apple Watch uses when it measures your heart rate in the background, and for heart rate notifications. Apple Watch uses green LED lights to measure your heart rate during workouts and Breathe sessions, and to calculate walking average and Heart Rate Variability (HRV).



<https://support.apple.com/en-us/HT204666#sensors>.

31. The Apple Watch Series 5 includes an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device.

Apple Watch Series 4, Series 5, or Series 6* also have built-in electrodes in the Digital Crown and the back of Apple Watch, which can measure the electrical signals across your heart when used with the Heart Rate app or the ECG app. When you place your finger on the Digital Crown, it creates a closed circuit between your heart and both arms, capturing the electrical impulses across your chest.

<https://support.apple.com/en-us/HT204666#sensors>.

32. The Apple Watch Series 5 includes a display operatively coupled to the processing device.



<https://support.apple.com/en-us/HT204666#sensors>.

33. The Apple Watch Series 5 includes a memory, operatively coupled to the processing device, the memory having instructions stored thereon.

Series 5

32
GB

Capacity 32GB

GPS + Cellular

32
GB

Capacity 32GB

GPS

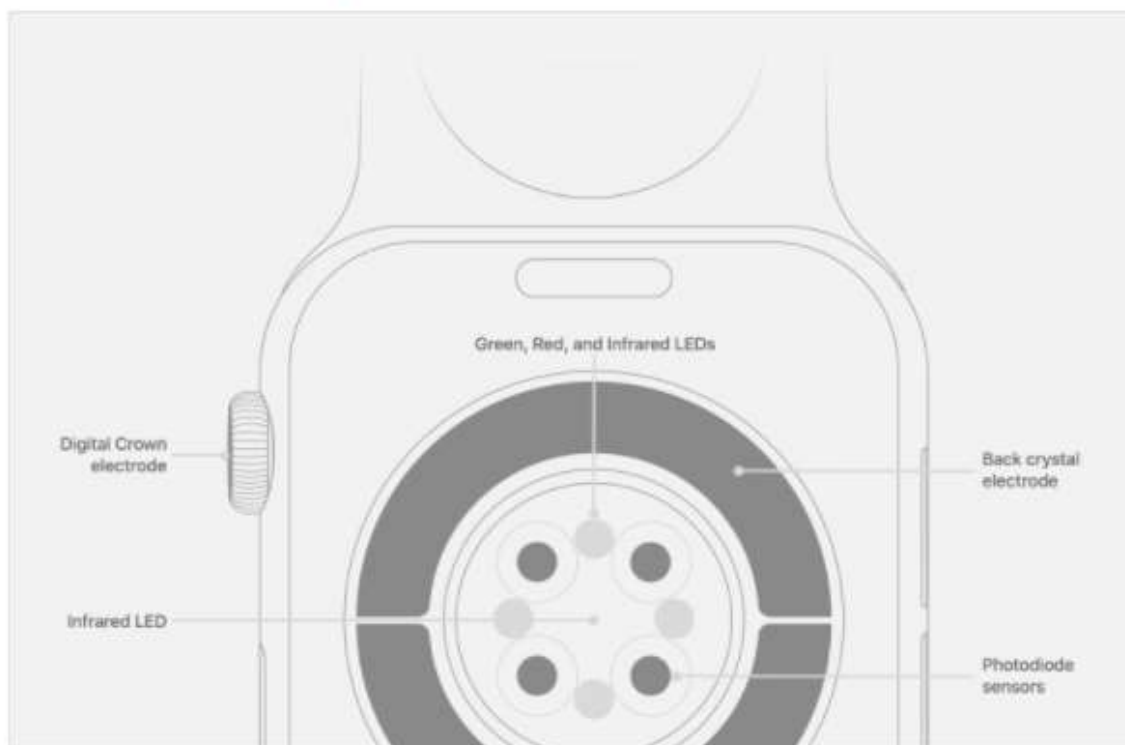
<https://www.apple.com/watch/compare/>.

34. The Apple Watch Series 5 includes memory having instructions stored thereon that, when executed by the processing device, cause the processing device to receive PPG data from the PPG sensor.

How Apple Watch measures your heart rate

The optical heart sensor in Apple Watch uses what is known as photoplethysmography. This technology, while difficult to pronounce, is based on a very simple fact: Blood is red because it reflects red light and absorbs green light. Apple Watch uses green LED lights paired with light-sensitive photodiodes to detect the amount of blood flowing through your wrist at any given moment. When your heart beats, the blood flow in your wrist — and the green light absorption — is greater. Between beats, it's less. By flashing its LED lights hundreds of times per second, Apple Watch can calculate the number of times the heart beats each minute — your heart rate. The optical heart sensor supports a range of 30–210 beats per minute. In addition, the optical heart sensor is designed to compensate for low signal levels by increasing both LED brightness and sampling rate.

The optical heart sensor can also use infrared light. This mode is what Apple Watch uses when it measures your heart rate in the background, and for heart rate notifications. Apple Watch uses green LED lights to measure your heart rate during workouts and Breathe sessions, and to calculate walking average and Heart Rate Variability (HRV).




<https://support.apple.com/en-us/HT204666#sensors>.

35. The Apple Watch Series 5 includes memory having instructions stored thereon that, when executed by the processing device, cause the processing device to detect, based on the PPG data, the presence of an arrhythmia.

36. The Apple Watch Series 5 includes memory having instructions stored thereon that, when executed by the processing device, cause the processing device to receive ECG data from the ECG sensor.

Take an ECG

You can take an ECG at any time, when you're feeling symptoms such as a rapid or skipped heartbeat, when you have other general concerns about your heart health, or when you receive an **irregular rhythm notification**.

1. Make sure that your Apple Watch is snug and on the wrist that you selected in the Apple Watch app. To check, open the Apple Watch app, tap the My Watch tab, then go to General > Watch Orientation.
2. Open the ECG app  on your Apple Watch.
3. Rest your arms on a table or in your lap.
4. With the hand opposite your watch, hold your finger on the Digital Crown. You don't need to press the Digital Crown during the session.
5. Wait. The recording takes 30 seconds. At the end of the recording, you will receive a classification, then you can tap Add Symptoms and choose your symptoms.
6. Tap Save to note any symptoms, then tap Done.



<https://support.apple.com/en-us/HT208955>.

37. The Apple Watch Series 5 includes memory having instructions stored thereon that, when executed by the processing device, cause the processing device to confirm the presence of the arrhythmia based on the ECG data.

How the ECG app works

The ECG app on Apple Watch Series 4, Series 5, or Series 6 generates an ECG that is similar to a single-lead (or Lead I) ECG. In a doctor's office, a standard 12-lead ECG is usually taken. This 12-lead ECG records electrical signals from different angles in the heart to produce twelve different waveforms. The ECG app on Apple Watch measures a waveform similar to one of those twelve waveforms. A single-lead ECG is able to provide information about heart rate and heart rhythm and enables classification of AFib.

<https://support.apple.com/en-us/HT208955>.

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.

See also, e.g., September 11, 2018 FDA Letter to Apple, attached as Exhibit 5.

38. This description is based on publicly available information and a reasonable investigation of the structure and operation of the Apple Accused Products. AliveCor reserves the right to modify this description, including, for example, on the basis of information about the Apple Accused Products that it obtains during discovery.

39. Apple's infringement has damaged and continues to damage AliveCor in an amount yet to be determined, but at least a reasonable royalty and/or the lost profits that AliveCor would have made but for Apple's acts of infringement.

40. This is an exceptional case. AliveCor is entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of the infringement of the '731 Patent by Apple.

COUNT II

Apple's Infringement of U.S. Patent No 10,638,941

41. AliveCor restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

42. AliveCor is the owner, by assignment, of U.S. Patent No. 10,638,941, titled "Discordance monitoring." A true and correct copy of U.S. Patent No. 10,638,941 granted by the U.S. Patent & Trademark Office is attached as Exhibit 2.

43. Defendant Apple has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 12 of the '941 Patent by making, using, selling, and/or offering for sale its Apple Watch Series 4 and later devices with the ECG App (“Apple Accused Products”) in the United States, in violation of 35 U.S.C. § 271(a). See, e.g., <https://support.apple.com/guide/watch/ecg-apdea4c50a57/7.0/watchos/7.0>. Apple has also infringed, and is continuing to infringe, literally or under the doctrine of equivalents claims 16, 18, and 20-22 of the '941 Patent.

44. At least as of the filing of the complaint, Defendant Apple has knowledge of the '941 Patent.

45. As a non-limiting example, the Apple Watch Series 5 is a smartwatch.

“Your finger can tell you a lot about your heart. Electrodes built into the Digital Crown and the back crystal work together with the ECG app to read your heart’s electrical signals. Simply touch the Digital Crown to generate an ECG waveform in just 30 seconds. The ECG app can indicate whether your heart rhythm shows signs of atrial fibrillation — a serious form of irregular heart rhythm — or sinus rhythm, which means your heart is beating in a normal pattern.”

<https://www.apple.com/apple-watch-series-5/>.



<https://www.apple.com/healthcare/apple-watch/>.

46. The Apple Watch Series 5 includes a processor.

Series 5



64-bit dual-core S5 processor
Up to 2x faster than S3 processor

<https://www.apple.com/watch/compare/>.

47. The Apple Watch Series 5 includes a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor.

In addition, Apple Watch measures your heart rate throughout the day when you're still, and periodically when you're walking (Apple Watch Series 1 or later). Since Apple Watch takes these background readings based on your **activity**, the time between these measurements will vary. Apple Watch also calculates a daily resting rate and walking average by correlating background heart rate readings with accelerometer data when sufficient background readings are available. You

<https://support.apple.com/en-us/HT204666> (highlighting added).

48. The Apple Watch Series 5 includes a PPG sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor.

How Apple Watch measures your heart rate

The optical heart sensor in Apple Watch uses what is known as photoplethysmography. This technology, while difficult to pronounce, is based on a very simple fact: Blood is red because it reflects red light and absorbs green light. Apple Watch uses green LED lights paired with light-sensitive photodiodes to detect the amount of blood flowing through your wrist at any given moment. When your heart beats, the blood flow in your wrist — and the green light absorption — is greater. Between beats, it's less. By flashing its LED lights hundreds of times per second, Apple Watch can calculate the number of times the heart beats each minute — your heart rate. The optical heart sensor supports a range of 30–210 beats per minute. In addition, the optical heart sensor is designed to compensate for low signal levels by increasing both LED brightness and sampling rate.

The optical heart sensor can also use infrared light. This mode is what Apple Watch uses when it measures your heart rate in the background, and for heart rate notifications. Apple Watch uses green LED lights to measure your heart rate during workouts and Breathe sessions, and to calculate walking average and Heart Rate Variability (HRV).



<https://support.apple.com/en-us/HT204666#sensors>.

49. The Apple Watch Series 5 includes an ECG sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor.

Apple Watch Series 4, Series 5, or Series 6* also have built-in electrodes in the Digital Crown and the back of Apple Watch, which can measure the electrical signals across your heart when used with the Heart Rate app or the ECG app. When you place your finger on the Digital Crown, it creates a closed circuit between your heart and both arms, capturing the electrical impulses across your chest.

<https://support.apple.com/en-us/HT204666#sensors>.

50. The Apple Watch Series 5 includes a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor.

Series 5

32
GB

Capacity 32GB

GPS + Cellular

32
GB

Capacity 32GB

GPS

<https://www.apple.com/watch/compare/>.

51. The Apple Watch Series 5 includes instructions executable by the processor to cause the processor to determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user.

PPG-based arrhythmia detection

Technical and Feature Description

Apple Watch has an optical heart sensor that uses green LED lights paired with light-sensitive photodiodes to detect blood volume pulses in a user's wrist using photoplethysmography. These sensors and underlying algorithms are the basis for the heart rate and heart rate variability (HRV) detection enabled on Apple Watch Series 1 and later. To determine HRV, Apple Watch captures a tachogram, a plot of the time between heartbeats, every two to four hours. Beginning with watchOS 5.1.2, a user may also choose to enable an arrhythmia detection feature that utilizes these tachograms. To use the Irregular Rhythm Notification feature on Apple Watch, a user must first complete onboarding within the Health app on the user's paired iPhone to learn how to use the feature and receive education regarding AF. To learn more about the user experience, visit <https://support.apple.com/kb/HT208931>.

If the PPG-based arrhythmia detection is enabled, each tachogram is classified using a proprietary algorithm to determine if an irregular rhythm may be present. An irregular tachogram initiates a cascade of more frequent tachogram collection (as frequently as possible, subject to a minimum spacing of 15 minutes) and analysis. Tachograms are collected and analyzed only if the user remains still enough to obtain a reading; because of this, the algorithm is not always monitoring the user, but rather is doing so opportunistically when adequate signal is available for collection/analysis. If five out of six sequential

https://www.apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf.

52. The Apple Watch Series 5 includes instructions executable by the processor to cause the processor to, based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present.

How the ECG app works

The ECG app on Apple Watch Series 4, Series 5, or Series 6 generates an ECG that is similar to a single-lead (or Lead I) ECG. In a doctor's office, a standard 12-lead ECG is usually taken. This 12-lead ECG records electrical signals from different angles in the heart to produce twelve different waveforms. The ECG app on Apple Watch measures a waveform similar to one of those twelve waveforms. A single-lead ECG is able to provide information about heart rate and heart rhythm and enables classification of AFib.

<https://support.apple.com/en-us/HT208955>.

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.

See also, e.g., Ex. 5.

53. The Apple Watch Series 5 includes instructions executable by the processor to cause the processor to receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

How the ECG app works

The ECG app on Apple Watch Series 4, Series 5, or Series 6 generates an ECG that is similar to a single-lead (or Lead I) ECG. In a doctor's office, a standard 12-lead ECG is usually taken. This 12-lead ECG records electrical signals from different angles in the heart to produce twelve different waveforms. The ECG app on Apple Watch measures a waveform similar to one of those twelve waveforms. A single-lead ECG is able to provide information about heart rate and heart rhythm and enables classification of AFib.

<https://support.apple.com/en-us/HT208955>.

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.

See also, e.g., Ex. 5.

54. This description is based on publicly available information and a reasonable investigation of the structure and operation of the Apple Accused Products. AliveCor reserves the right to modify this description, including, for example, on the basis of information about the Apple Accused Products that it obtains during discovery.

55. Apple's infringement has damaged and continues to damage AliveCor in an amount yet to be determined, but at least a reasonable royalty and/or the lost profits that AliveCor would have made but for Apple's acts of infringement.

56. This is an exceptional case. AliveCor is entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of the infringement of the '941 Patent by Apple.

COUNT III

Apple's Infringement of U.S. Patent No 9,572,499

57. AliveCor restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

58. AliveCor is the owner, by assignment, of U.S. Patent No. 9,572,499, titled “Methods and systems for arrhythmia tracking and scoring.” A true and correct copy of U.S. Patent No. 9,572,499 granted by the U.S. Patent & Trademark Office is attached as Exhibit 3.

59. Defendant Apple has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 11 of the '499 Patent by making, using, selling, and/or offering for sale its Apple Watch Series 4 and later devices with the ECG App (“Apple Accused Products”) in the United States, in violation of 35 U.S.C. § 271(a). See, e.g., <https://support.apple.com/guide/watch/ecg-apdea4c50a57/7.0/watchos/7.0>. Defendant Apple has also infringed, and is continuing to infringe, literally or under the doctrine of equivalents, claim 16.

60. At least as of the filing of the complaint, Defendant Apple has knowledge of the '499 Patent.

61. As a non-limiting example, the Apple Watch Series 5 is a system for determining the presence of an arrhythmia of a first user, comprising a heart rate sensor coupled to said first user.

“Your finger can tell you a lot about your heart. Electrodes built into the Digital Crown and the back crystal work together with the ECG app to read your heart’s electrical signals. Simply touch the Digital Crown to generate an ECG waveform in just 30 seconds. The ECG app can indicate whether your heart rhythm shows signs of atrial fibrillation — a serious form of irregular heart rhythm — or sinus rhythm, which means your heart is beating in a normal pattern.”

<https://www.apple.com/apple-watch-series-5/>.



<https://www.apple.com/healthcare/apple-watch/>.

62. The Apple Watch Series 5 includes a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user.



<https://www.apple.com/healthcare/apple-watch/>.

Series 5



64-bit dual-core S5 processor
Up to 2x faster than S3 processor

<https://www.apple.com/watch/compare/>.

How Apple Watch measures your heart rate

The optical heart sensor in Apple Watch uses what is known as photoplethysmography. This technology, while difficult to pronounce, is based on a very simple fact: Blood is red because it reflects red light and absorbs green light. Apple Watch uses green LED lights paired with light-sensitive photodiodes to detect the amount of blood flowing through your wrist at any given moment. When your heart beats, the blood flow in your wrist — and the green light absorption — is greater. Between beats, it's less. By flashing its LED lights hundreds of times per second, Apple Watch can calculate the number of times the heart beats each minute — your heart rate. The optical heart sensor supports a range of 30–210 beats per minute. In addition, the optical heart sensor is designed to compensate for low signal levels by increasing both LED brightness and sampling rate.

The optical heart sensor can also use infrared light. This mode is what Apple Watch uses when it measures your heart rate in the background, and for heart rate notifications. Apple Watch uses green LED lights to measure your heart rate during workouts and Breathe sessions, and to calculate walking average and Heart Rate Variability (HRV).



<https://support.apple.com/en-us/HT204666#sensors>.

“Your finger can tell you a lot about your heart. Electrodes built into the Digital Crown and the back crystal work together with the ECG app to read your heart’s electrical signals. Simply touch the Digital Crown to generate an ECG waveform in just 30 seconds. The ECG

app can indicate whether your heart rhythm shows signs of atrial fibrillation — a serious form of irregular heart rhythm — or sinus rhythm, which means your heart is beating in a normal pattern.”

<https://www.apple.com/apple-watch-series-5/>.

63. The Apple Watch Series 5 includes a motion sensor.

In addition, Apple Watch measures your heart rate throughout the day when you're still, and periodically when you're walking (Apple Watch Series 1 or later). Since Apple Watch takes these background readings based on your activity, the time between these measurements will vary. Apple Watch also calculates a daily resting rate and walking average by correlating background heart rate readings with accelerometer data when sufficient background readings are available. You

<https://support.apple.com/en-us/HT204666>.

64. The Apple Watch Series 5 includes a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and [sic] activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

Series 5

32
GB

Capacity 32GB

GPS + Cellular

32
GB

Capacity 32GB

GPS

<https://www.apple.com/watch/compare/>.

In addition, Apple Watch measures your heart rate throughout the day when you're still, and periodically when you're walking (Apple Watch Series 1 or later). Since Apple Watch takes these background readings based on your activity, the time between these measurements will vary. Apple Watch also calculates a daily resting rate and walking average by correlating background heart rate readings with accelerometer data when sufficient background readings are available. You

<https://support.apple.com/en-us/HT204666>.

Apple Watch Series 4, Series 5, or Series 6* also have built-in electrodes in the Digital Crown and the back of Apple Watch, which can measure the electrical signals across your heart when used with the Heart Rate app or the ECG app. When you place your finger on the Digital Crown, it creates a closed circuit between your heart and both arms, capturing the electrical impulses across your chest.

<https://support.apple.com/en-us/HT204666#sensors>.

PPG-based arrhythmia detection

Technical and Feature Description

Apple Watch has an optical heart sensor that uses green LED lights paired with light-sensitive photodiodes to detect blood volume pulses in a user's wrist using photoplethysmography. These sensors and underlying algorithms are the basis for the heart rate and heart rate variability (HRV) detection enabled on Apple Watch Series 1 and later. To determine HRV, Apple Watch captures a tachogram, a plot of the time between heartbeats, every two to four hours. Beginning with watchOS 5.1.2, a user may also choose to enable an arrhythmia detection feature that utilizes these tachograms. To use the Irregular Rhythm Notification feature on Apple Watch, a user must first complete onboarding within the Health app on the user's paired iPhone to learn how to use the feature and receive education regarding AF. To learn more about the user experience, visit <https://support.apple.com/kb/HT208931>.

If the PPG-based arrhythmia detection is enabled, each tachogram is classified using a proprietary algorithm to determine if an irregular rhythm may be present. An irregular tachogram initiates a cascade of more frequent tachogram collection (as frequently as possible, subject to a minimum spacing of 15 minutes) and analysis. Tachograms are collected and analyzed only if the user remains still enough to obtain a reading; because of this, the algorithm is not always monitoring the user, but rather is doing so opportunistically when adequate signal is available for collection/analysis. If five out of six sequential

https://www.apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf.

How the ECG app works

The ECG app on Apple Watch Series 4, Series 5, or Series 6 generates an ECG that is similar to a single-lead (or Lead I) ECG. In a doctor's office, a standard 12-lead ECG is usually taken. This 12-lead ECG records electrical signals from different angles in the heart to produce twelve different waveforms. The ECG app on Apple Watch measures a waveform similar to one of those twelve waveforms. A single-lead ECG is able to provide information about heart rate and heart rhythm and enables classification of AFib.

<https://support.apple.com/en-us/HT208955>.

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.

See also, e.g., Ex. 5.

ECG app.

With the ECG app on Apple Watch Series 4 or later, patients who experience symptoms such as rapid or skipped heartbeat, or receive the irregular rhythm notification, can capture an ECG and record their symptoms. This real world data can enable you to make more informed and timely decisions regarding further evaluation and care.

<https://www.apple.com/healthcare/apple-watch/>.

65. This description is based on publicly available information and a reasonable investigation of the structure and operation of the Apple Accused Products. AliveCor reserves the right to modify this description, including, for example, on the basis of information about the Apple Accused Products that it obtains during discovery.

66. Apple's infringement has damaged and continues to damage AliveCor in an amount yet to be determined, but at least a reasonable royalty and/or the lost profits that AliveCor would have made but for Apple's acts of infringement.

67. This is an exceptional case. AliveCor is entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of the infringement of the '499 Patent by Apple.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial for all issues deemed to be triable by a jury.

PRAYER FOR RELIEF

WHEREFORE, AliveCor requests the Court grant the relief set forth below:

A. Enter judgment that Defendant has infringed, and continues to infringe, one or more claims of the '731 Patent, the '941 Patent, and/or the '499 Patent;

B. Temporarily, preliminarily, or permanently enjoin Defendant, their parents, subsidiaries, affiliates, divisions, officers, agents, servants, employees, directors, partners, representatives, all individuals and entities in active concert and/or participation with them, and all individuals and/or entities within their control from engaging in the aforesaid unlawful acts of patent infringement;

C. Order Defendant to account for and pay damages caused to AliveCor by Defendant's unlawful acts of patent infringement;

D. Award AliveCor increased damages and attorney fees pursuant to 35 U.S.C. §§ 284 and 285;

E. Award AliveCor the interest and costs incurred in this action; and

F. Grant AliveCor such other and further relief, including equitable relief, as the Court deems just and proper.

DATED: December 7, 2020

Respectfully submitted,

By /s/ J. Mark Mann

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