KardiaMobile 6L System

Inpatient User Guide
New FDA Guidance Allows Use of KardiaMobile 6L to Measure QTc in COVID-19 Patients

World’s only FDA-cleared six-lead personal ECG will be used by healthcare professionals to monitor QT duration in patients receiving medications that can cause potentially life-threatening QT prolongation

MOUNTAIN VIEW, Calif., March 23, 2020 — AliveCor, the leader in artificial intelligence (AI)-based, personal ECG technology, and provider of enterprise cardiology solutions, today announced that its KardiaMobile 6L — the world’s only six-lead personal ECG — is now allowed for use in the measurement of a patient’s QTc and detection of potentially dangerous QT prolongation. A prolonged QTc can lead to a potentially fatal side effect, called drug-induced sudden cardiac death (DI-SCD), associated with the use of several medicines now being used in the treatment of COVID-19 across the country, and to further expand AliveCor’s global footprint.

QT Analysis results displayed in KardiaPro are adjunctive and should not be solely or primarily relied upon to treat COVID-19 or co-existing conditions.

To view the entire announcement, visit: click here.
KardiaMobile 6L System

Inpatient Use

When using KardiaMobile 6L in a hospital setting, you will need:

- KardiaMobile 6L device
- KardiaStation application installed on mobile phone(s) and/or tablet(s)
- KardiaPro web-based portal
Inpatient User Guide

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The Inpatient User Guide provides detailed instructions including setup, recording an ECG, and accessing the ECG and QT Analysis results.

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INPATIENT USER GUIDE

Getting ready to implement KardiaMobile 6L System in your hospital

SETUP

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• Inpatient Use Cases for QTc Monitoring
• KardiaStation
• KardiaStation Setup
• KardiaMobile 6L
• KardiaMobile 6L Setup
• Pairing KardiaMobile 6L
• KardiaPro
• KardiaPro Setup
Inpatient Use Cases for QTc Monitoring

Role of Cardiology

There are several workflow options for the medication management of COVID-19 patients in need of QTc monitoring depending on how your hospital chooses to utilize your cardiology department.

**USE CASE 1**
Insufficient resources for cardiology consult every time a QTc measurement is needed for medication management

- KardiaMobile 6L ECG recordings are sent to an independent testing facility for QT Analysis
- Prescribing physician accesses results to inform medication management

**USE CASE 2**
Cardiology reviews all QT results or only prolonged QT results

- KardiaMobile 6L ECG recordings are sent to an independent testing facility for QT Analysis
- Results are accessed by cardiologist who adds interpretation to ECG
- Prescribing physician accesses results and interpretation to inform medication management

**USE CASE 3**
Cardiology conducts QTc measurements directly from ECG

- Cardiology access ECG recording and conducts QTc measurement directly from an ECG recording
- QTc results and interpretation are added to ECG
- Prescribing physician accesses results and interpretation to inform medication management
AliveCor®
KardiaStation

KardiaStation Application

Artificial Intelligence–enabled platform for clinicians to record six-lead ECGs from KardiaMobile 6L devices.
KardiaStation Setup
Smart Device Compatibility

KardiaStation is available on Apple products via the App Store.

You can implement as many devices with KardiaStation as needed in your hospital.

Tip: When you see “your mobile phones or tablets” in this guide, it is referring to the device(s) with KardiaStation installed.
KardiaStation Setup

Installation

1. Search for “KardiaStation” in the App Store.

2. Download and install.

If you are using KardiaMobile 6L for QTc monitoring then you will need to download “KardiaStation Professional”, which is only available in the App Store at this time.

Tip: Make sure you download “KardiaStation” not “Kardia App.”
KardiaStation Setup

Logging in

1. Open the KardiaStation app.

2. Enter user email and password
   If you do not have the login information, please see the individual in your hospital who manages your AliveCor account.

3. Select “Log in.”

Please note: “Request Access” is intended only for organizations that have not contracted for KardiaStation access yet.
KardiaMobile 6L Device

KardiaMobile 6L is a six-lead personal ECG. This device delivers ECG Leads I, II, III, aVL, aVR, and aVF. It is the only FDA-cleared personal ECG that includes Lead II, which is the most critical for assessing patients for QT prolongation.
KardiaMobile 6L

About the Device

KardiaMobile 6L is a 3-electrode personal ECG device that records an ECG and wirelessly transmits the data to your mobile phone or tablet using KardiaStation.

- Contains two electrodes on the top surface, for use with the left and right hands, and one on the bottom surface, for use with the bare skin of the left leg or lower left abdomen
- Powered by a replaceable battery located under the bottom electrode

Tips: You can access additional technical information about the KardiaMobile 6L in the Instructions for Use (outpatient) at support.alivecor.com.

Placement on the lower left abdomen is for inpatient use only when the patient cannot reach the recommended placement options on the left leg.
KardiaMobile 6L

Lead-II Critical for QT Analysis

KardiaMobile 6L is capable of recording a single-lead (1L) or a six-lead (6L) ECG.

When using the ECG to determine QT prolongation, a 6L ECG should be used in order to collect Lead-II data for QT measurement.

- Corrected QT (QTc) measurements calculated from Lead II are the most unbiased compared to other leads
- Threshold values defining prolonged QT are based on Lead-II calculations
- QTc calculated from other leads could potentially result in inappropriate medication decisions

KardiaMobile 6L Setup

Tagging the Device for Patient Identification

The serial number is located on the KardiaMobile 6L device packaging. This unique identifier for the device is the last nine digits of the barcode.

Due to the close proximity of multiple KardiaMobile 6L devices in the unit, it is possible that KardiaStation could pick up the Bluetooth signal of an unintended device up to 30 feet away.

Therefore, for patient safety purposes, you will be asked to verify the 6L device serial number each time you record an ECG.

Since the serial number is not printed on the outside of the device, *you must label the serial number on each device* to be used in the verification process.

When you take your device out of the box, write the serial number on a sticker and affix to one of the black plastic areas on the back of the device.

Make sure you do not cover any part of the silver electrode.

1. In this example from a KardiaMobile 6L box, the serial number is underlined: +B210ACD1090/55+$720012673L.

2. A sticker with the serial number written on it has been affixed to the bottom of the KardiaMobile 6L device.

* The serial number is printed under the bottom electrode of the device. You must remove the battery to access the serial number.
Pairing KardiaMobile 6L

Pairing the Device With KardiaStation

The first time KardiaMobile 6L interacts with KardiaStation, you will be prompted to pair the device when you are recording an ECG.

- You will not have to pair the two devices again regardless of how many KardiaMobile 6L devices you pair
- You can choose to test each device and pair them prior to first use, or allow the pairing to occur during use with patient
- The first time you use KardiaStation, the application will ask for permission to use your mobile phone or tablet’s Bluetooth

If you choose to pair the devices prior to patient use:

1. Select “Record an EKG.”
2. Enter “Test” or any alpha numeric combination.
   - Select “Pair”

Tip: If the KardiaMobile 6L is not recognized by KardiaStation, make sure Bluetooth is enabled on your mobile phone or tablet.
KardiaPro is a HIPAA-compliant web-based portal to access your patients’ ECG recordings and QT Analysis results from anywhere.

Several of the functions in KardiaPro are specifically for the outpatient setting and are not applicable for inpatient use.
KardiaPro Setup

First Time Signing in

These instructions are intended for the account administrator at your hospital only.

1. Simply enter [www.kardiaapro.com](http://www.kardiaapro.com) into your web browser.

2. Select “Forgot password?”
   - Enter email address as your username
   - You will receive an email to create a secure password to sign in to KardiaPro.

If you are a KardiaPro user at your hospital and need access, your account administrator can grant you access (see User Settings).
Recording an ECG

**INPATIENT USER GUIDE**

Using KardiaMobile 6L to record patients’ ECGs

**RECORDING AN ECG**

- Initiating KardiaStation
- Positioning KardiaMobile 6L
- Getting Instant Cardiac Rhythm Assessment Results
- Instant Analysis Descriptions
- Requesting QT Analysis
**Recording an ECG**

**Initiating KardiaStation**

1. Open the KardiaStation app on your mobile phone or tablet.
2. Select “Record an EKG.”
3. Enter MRN or Patient ID.
   - Any alpha numeric combination
   - This is how patients will be identified in KardiaPro, so make sure the entry is correct
4. Confirm:
   a. 6L serial number
   b. MRN or Patient ID
   - Select “Continue”
5. Confirm “Six-lead EKG” is selected.
   - Although the KardiaMobile 6L can record a single-lead ECG, a 6L ECG should always be used for QT Analysis

MRN = Medical Record Number

If device pairing was not done during set up, you will receive a notification “Bluetooth Pairing Request” after you enter the MRN. Select “Pair.”
Recording an ECG

Positioning KardiaMobile 6L

Assist the patient with positioning the 3 electrodes of the KardiaMobile 6L.

1. Instruct the patient to place fingers or thumbs on the top left and right electrodes.
   - Make sure the device is in the correct orientation, with the AliveCor “/” pointing forward (as pictured)

2. Select placement option for the electrode on the bottom of the 6L device:
   a. If sitting up, above left knee
   b. If supine, lower left quadrant of abdomen

3. ECG will begin recording when good skin contact is made on all 3 electrodes.
   - Each electrode on the screen will turn green when a good contact is made

Tips: Too much body fat or body hair will prevent a good bare skin contact.

If the patient has dry skin, moisten with water. This is especially true for the leg or abdomen placement to ensure good skin contact throughout the recording.
Recording an ECG

Getting Instant Cardiac Rhythm Assessment Results

1. Instruct the patient to hold still during the 30-second ECG recording.

2. If you get either of the notifications:
   a. “Your EKG was interrupted” and too short to analyze
   b. “Recording was unreadable due to interference”
      • Select “Record Again”

3. When finished recording, KardiaStation will display a cardiac rhythm assessment.
   • Examples showing Normal Sinus Rhythm and Possible Atrial Fibrillation
   • ECG recordings with instant heart rhythm analysis results are immediately available in KardiaPro
KardiaStation

Instant Analysis Descriptions

Upon completion of an ECG recording, KardiaMobile 6L transmits the ECG data to KardiaStation.

The ECG is then processed by AliveCor’s Instant Analysis algorithms.

KardiaStation will display the full six-lead ECG and one of the following Instant Analysis results:

- Possible Atrial Fibrillation
- Bradycardia
- Tachycardia
- Normal
- Unclassified
- Too Short
- Unreadable

If required, consult cardiology.

<table>
<thead>
<tr>
<th>Instant Analysis Result</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible Atrial Fibrillation</td>
<td>ECG shows signs of atrial fibrillation</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>Heart rate is less than 50 beats per minute</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>Heart rate is more than 100 beats per minute</td>
</tr>
<tr>
<td>Normal</td>
<td>No rhythm abnormalities detected in ECG</td>
</tr>
<tr>
<td>Unclassified</td>
<td>Atrial fibrillation was not detected and the ECG does not fall under the algorithmic classifications of Normal, Bradycardia, or Tachycardia. This may be caused by other arrhythmias, unusually fast or slow heart rates, or poor quality recordings.</td>
</tr>
<tr>
<td>Too Short</td>
<td>ECG recording is of insufficient duration. Instant Analysis is not able to provide an analysis on ECG recordings shorter than 30 seconds. Re-record ECG.</td>
</tr>
<tr>
<td>Unreadable</td>
<td>There is too much interference in the recording. Re-Record ECG.</td>
</tr>
</tbody>
</table>

**WARNING:** After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy and ventricular trigeminy heart conditions as unreadable.
Recording an ECG

Requesting QT Analysis

QTc calculations are not a part of the Instant Analysis. AliveCor’s independent testing facility will calculate QTc from the ECG upon request.

1. If you want to request a QT Analysis*
   a. Select “Request QT Analysis”
   b. If requested, you will be asked to confirm your request
      • QT Analysis results will be available in KardiaPro in approximately one hour

2. Select “Done” to complete.
   • Once you select “Done”, you will not be able to access the ECG in KardiaStation
   • The ECG can be accessed immediately in KardiaPro
   • If you forget to “Request QT Analysis”, access the ECG in KardiaPro where you can also request a QT Analysis of that ECG

At this time, you cannot tell which ECG has QT Analysis results from this list of ECGs. You must select and view a specific ECG to see QT Analysis results.

*QTc Analysis is performed by an independent testing facility.
Skip this step if you are calculating QTc on your own.
INPATIENT USER GUIDE

Using KardiaPro to access your patients’ ECG recordings and QT Analysis results

ACCESSING AN ECG AND QT RESULTS

- KardiaPro Dashboard
- KardiaPro Patient Directory
- KardiaPro Reviewing a Patient File
- Reviewing ECGs
- KardiaPro User Settings

Accessing an ECG and QT Analysis results
KardiaPro

Dashboard

From this homepage, you can access all the areas of KardiaPro.

1. Patients: Access the list of patients in your hospital that have data.
2. ECG Inbox: Access both your Personal Inbox or the Hospital’s Inbox. Here you will find ECGs that have been flagged* for review.
3. Reports: Automatic reports for billing are for outpatient use only and not applicable for inpatient use.
4. Connection Metrics: This function is for outpatient use only and not applicable for inpatient use.
5. Add Patient: If you choose, you can add a new patient to KardiaPro before any ECGs are recorded in KardiaStation. Otherwise, the patient record is created when the ECG is recorded, based on the MRN entered.
6. Settings: All users can update their password here. Account Administrators have access to add and delete team members, set email notification frequency, and set default inbox settings.
7. Sign Out: Sign out of KardiaPro here. If you forget to sign out, the system will automatically sign you out after 20 minutes of inactivity.

* At this time, QT results cannot be flagged for review and automatically sent to your ECG Inbox.
KardiaPro

Patient Directory

The patient directory is used to search for a specific patient. Once in a patient file, you have access to all of the ECG recordings and QT Analysis results. You can also see notes, summary reports, and blood pressure data (if entered).

1. Select “Patients.”
2. To quickly find a specific patient, type the MRN (medical record number) in the search field.
   - If name was entered into the Patient Profile in KardiaPro, you can also search on patient first or last name. Otherwise, only the MRN or Patient ID that was used in KardiaStation will be listed
   - To return to the full list of patients when finished, press the “x” next to the patient’s name in the search field
3. Select any row to open a patient’s file.
KardiaPro

Reviewing a Patient File

1. Overview – Outpatient only
   - If patient has an outpatient connection plan, this tab would be an overview of the connection

2. Profile
   - Add and edit patient name, DOB, and additional personal information

3. Reports – Outpatient only

4. ECG
   - Review ECG recordings and QT Analysis results

5. Blood Pressure – Outpatient only
   - Additional information on blood pressure readings if available

6. Weight – Outpatient only
   - Additional information on weight measurements if available
KardiaPro

Reviewing a Patient File, continued (Profile)

1. "Profile" tab of Patient File.
2. Patient demographic information, all fields are modifiable by selecting the pencil icon.
   - Patient email is not used in the inpatient setting. A dummy email can be entered
3. Access and modify notes section in concert with key points regarding patient care plan.
4. KardiaPro connection history is applicable to outpatient setting only.

If you desire patient information to appear on ECG recordings and reports then patient information must be completed in the Patient Profile.
KardiaPro

Reviewing a Patient File, continued (ECG)

1. "ECG" tab of Patient File.
2. Use the scroll bar under the ECG graph to quickly scroll through months of ECGs to see visual representation for how frequently the patient is in and out of sinus rhythm. Tap on a dot in the graph to bring the ECG recordings to the top of the list.
3. View all ECGs this patient has recorded.
4. Open any ECG to access QT Analysis results and/or apply interpretations.
   - 6L ECGs are marked with "6L" compared to 1L ECGs. QT results are only available on 6L ECGs.

At this time, you cannot tell which ECG has QT Analysis results from this list of ECGs. You must select and view a specific ECG to see QT Analysis results.
Reviewing ECGs (QT Analysis Request)

1. QT Analysis status
2. Request QT Analysis button

The following tables summarizes the status options for the QT Analysis results

<table>
<thead>
<tr>
<th>Status</th>
<th>Request QT Analysis button</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis not requested</td>
<td>Not requested Green “Request Analysis” button</td>
</tr>
<tr>
<td>Analysis requested</td>
<td>Pending “Request Analysis” button grayed out</td>
</tr>
<tr>
<td>Results completed</td>
<td>Completed No button visible</td>
</tr>
</tbody>
</table>

* QT Analysis can be requested in KardiaPro by clicking on button.

* Regardless of whether the QT Analysis was requested in KardiaStation or KardiaPro.
Reviewing ECGs, continued

(QT Analysis Results)

The following results are presented from the QT Analysis:

1. QT: raw QT interval (not corrected)
2. RR: the R-R interval
3. QTc: corrected QT interval calculated using the Bazett formula:

\[
\text{QTc} = \frac{\text{QT interval in seconds}}{\sqrt{\text{cardiac cycle in seconds}}} = \frac{\text{QT}}{\sqrt{\text{RR}}}
\]

The QT and R-R interval are essential for the verification of the QTc calculation result.
Reviewing ECGs, continued
(Adding Interpretation)

REVIEWING, INTERPRETING & SIGNING:

1. Type in box or scroll to search for an interpretation. Time-saving tip: You can easily search for “Ventricular Premature Complex” by typing “PVC” in the search bar. Additionally, you can select more than one interpretation. The interpretations selected will appear in the “added interpretations” section.

2. Optional: Type additional comments or notes. In order to add comments or notes, an interpretation must be selected in step 1.

3. Select “Save.”

Hospitals in which Cardiology will be reviewing QT Analysis results or will be conducting QTc measurements themselves can use the Interpretation function to add their findings to the ECG.
Reviewing ECGs, continued (Interpretation Workflow)

AFTER SAVING YOUR INTERPRETATION, YOU CAN EITHER

1. Select “Reassign” to send ECG to a different KardiaPro Inbox for review. The user must have a user account in your organization’s KardiaPro account.

OR

2. Select “Confirm” to save in the patient’s KardiaPro file and add to summary report.

By confirming, you will no longer be able to add or modify interpretations to this ECG. Confirmed ECGs will be listed in the archived folder. Option to bulk export confirmed ECGs from the archived folder.

OTHER ACTIONS

3. Select “Remove from Inbox” to remove the ECG from your ECG Inbox workflow. The ECG is saved to the patient’s KardiaPro file and added to the summary report.

4. Download an individual ECG as a PDF file in one click.

5. Go to a patient’s file to view the patient’s other ECGs. Then easily use your browser back button to return to interpreting this ECG recording.
KardiaPro

User Settings

From Settings, all users can change their password. For personnel designated as Account Administrators, you can add and remove members and modify Inbox default settings.

**ALL KARDIAPRO USERS: UPDATE PASSWORD**

1. Select “Settings.”
2. “Update Password” tab of Settings.
3. Enter your Current Password.
4. Enter your New Password twice.
5. Select “Save.”

Alternatively, if you don’t know your password and you’d like to reset your password, you can go to kardiapro.com and click “forgot password.” Enter your email. This will generate an email with a link to reset your password.
KardiaPro

User Settings, continued

ACCOUNT ADMINISTRATOR: INVITE MEMBER

1. Click “Invite Member” tab in the Settings Menu Bar.
2. Enter email address for new user.
3. Designate member role of either Account Administrator or Provider, by checking the appropriate box, if either role applies to the new member being invited. Administrators will be able to manage team member accounts and Inbox settings. Providers will be listed as an Ordering Provider when adding new patients. Invited member will receive an email with a link to create their KardiaPro account and password.
4. Pending Invites can be revoked by checking the email and selecting “Revoke.”

For documentation purposes, create a member login for every user, as opposed to a unit login that everyone shares, since actions taken in the system, such as ECG interpretations, get marked by the specific user.
**KardiaPro**

User Settings, continued

**ACCOUNT ADMINISTRATOR: MEMBER INFORMATION**

1. "Team Members" tab of Settings.
2. Search by name or email by selecting “Filter.”
3. Quickly filter or sort list by Administrators and Providers.
4. You can open any team member information by selecting any row (see next page for details).
KardiaPro
User Settings, continued

ACCOUNT ADMINISTRATOR: MEMBER INFORMATION

1. Edit name and email address.
2. Modify Member Roles.
3. Designate Unread ECG Reminders
   Email notifications.
4. Edit “Frequency of Reminders” to Daily, Weekly, or Never.
5. Receive reminders for ECGs in the Practice Inbox or the Personal Inbox.
6. Select “Save.”
KardiaPro
User Settings, continued

ACCOUNT ADMINISTRATOR: INBOX SETTINGS

1. “Inbox Settings” tab of Settings.

2. Select the practice level default for which recordings to flag: All non-normal recordings, All Recordings, No Recordings, or Custom.

3. Select “Save.”

Note: The inbox settings tab sets the default that will appear when a user is adding a new patient. However, you can always modify the “default inbox settings” for each patient upon patient enrollment or within the overview tab of the patient file.
Other Functions and Information

INPATIENT USER GUIDE

This section contains useful information for administrators or coordinators that maintain KardiaStation, KardiaMobile 6L, and KardiaPro.

OTHER FUNCTIONS AND INFORMATION

• KardiaStation Additional Menu Items
• KardiaMobile 6L Technical Considerations
KardiaStation

Additional Menu Options

1. The menu has additional options.
   • Password entry is needed to access and prevent logout from users
2. Changing the device pre-set.
   • Devices should pair automatically without having to do so through menu
   • Default for KardiaStation is the KardiaMobile 6L
   • Shows the list of ECGs that have been uploaded to KardiaPro
   • If your recorded ECG does not appear in KardiaPro, you may have lost your connection to transmit data from your mobile phone or tablet
4. About KardiaStation.
   • Application technical details
5. Log out.
KardiaMobile 6L Technical Considerations

The expected service life for KardiaMobile 6L is two years.
The device is powered by a CR2016 Coin Cell that is IEC 60086-4 compliant.
KardiaMobile 6L is IP22 rated. KardiaMobile 6L is protected against insertion of fingers and is not affected by vertically dripping water. KardiaMobile 6L has been tested with relevant requirement standard IEC 60601-1-11:2015.

**DO NOT** use the electrode on a portion of the body with too much body fat, body hair, or very dry skin, as a successful recording may not be possible.
**DO NOT** take a recording if electrodes are dirty. Clean them first.
**DO NOT** immerse device or expose device to excessive liquid.
**DO NOT** use while charging your smart device.
**DO NOT** drop or bump with excessive force.
**DO NOT** expose to strong electromagnetic fields.
**DO NOT** expose the device to a magnetic resonance (MR) environment.
**DO NOT** use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
**DO NOT** use during cauter y and external defibrillation procedures.
**DO NOT** place electrodes in contact with other conductive parts including earth.
**DO NOT** use with un-approved accessories. Use of non-AliveCor approved accessories or transducers and cables could result in electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
**DO NOT** use adjacent to or stacked with other equipment because it could result in improper operation.
**DO NOT** use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the KardiaMobile 6L System. Otherwise, degradation of the performance of the KardiaMobile 6L System could result.

For a full list of warnings and environment considerations, consult the “Instructions for Use for KardiaMobile 6L.”