

BRIEFING DOCUMENT

**KardiaMobile 6L to be Used to Measure and Monitor for  
QT Prolongation in COVID-19 Patients Receiving QT  
Prolonging Medicines**

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**AliveCor®**

## I. Background

The 2019 coronavirus, known as SARS-CoV-2 or COVID-19, is a global pandemic which is rapidly spreading throughout the world, with over 400,000 confirmed cases as of today.<sup>1</sup> Healthcare systems in the US and worldwide are struggling to keep up with an increase in demand for medical equipment and personnel. We are also seeing that the spreading disease is infecting the already stretched supply of healthcare professionals needed to address the pandemic requiring them to self-quarantine, further exacerbating the shortage. Scientists throughout the world are focused on developing vaccines and finding the treatment to cure this fatally infectious disease.




### A. Cardiotoxic Side-Effects of COVID-19 Experimental Therapies

Recently, the US FDA and CDC announced a large clinical trial to evaluate the efficacy and safety of two well-known antibiotics which have shown to have promising results in the battle against COVID-19, hydroxychloroquine and azithromycin.<sup>2</sup> Doctors prescribing these medicines have seen improvements in patients taking these medicines alone, or in combination. While the prospect of discovering potentially life-saving medicines is encouraging, caution must be taken when using these medicines as they are known to cause QT prolongation, a deadly side effect that increases the risk of torsades de pointes, a ventricular arrhythmia that can lead to cardiac arrest, or worse, sudden cardiac death (SCD).<sup>2,3,4</sup>

### B. ECG Monitoring During COVID-19 Crisis

The need to monitor for QT prolongation typically requires the use of a 12-lead ECG to capture Leads II, V5, or V6, which are traditionally used to measure and monitor the QT interval. An ECG is typically conducted by an ECG technician who is trained in proper lead placement to obtain a quality ECG. However, COVID-19 presents unique challenges in meeting ECG monitoring demands of patients as described in Table 1.

**Table 1: Challenges of ECG Monitoring in COVID-19 Patients**

 Capacity	 Infection control precautions	 Medication management
<ul style="list-style-type: none"><li>• Minimize transport of patients in hospital setting</li><li>• Insufficient number of mobile ECGs given infection control challenges</li><li>• Takes 10-15 minutes to complete</li></ul>	<ul style="list-style-type: none"><li>• Traditional ECG machines may be difficult to adequately disinfect between patient use</li><li>• Requires close contact by healthcare professionals</li></ul>	<ul style="list-style-type: none"><li>• Hydroxychloroquine and azithromycin can cause QT prolongation</li><li>• Safe use of these medications should involve QT monitoring before dosing</li></ul>

<sup>1</sup> [Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering \(CSSE\) at Johns Hopkins University \(JHU\)](#)

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html>

<sup>3</sup> <https://www.crediblemeds.org>

<sup>4</sup> [https://mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/jmcp\\_covid19.pdf](https://mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/jmcp_covid19.pdf)

## II. KardiaMobile 6L Emergency Use Authorization FDA Request

In an already resource-strapped healthcare system facing shortages in both medical supplies and personnel, and the high risk of transmission of COVID-19 to healthcare professional and other patients, the need for tools that allows for remote patient monitoring is critical. To this end, on March 19, 2020, AliveCor met with the FDA to discuss the emergency use of our KardiaMobile 6L device under the [FDA Emergency Use Authorization Guidance](#) to remotely monitor patients receiving these potentially life-saving medicines that are known to have cardiotoxic effects. AliveCor envisions that healthcare professionals on the frontlines of battling the COVID-19 pandemic can obtain a 6-lead ECG, print out the PDF copy, and measure the QT interval, RR interval, and calculate the corrected QT to make remote, medically informed decisions on treating the patient.

The AliveCor team presented the FDA with the aforementioned Table 1 to describe the challenges seen in obtaining ECGs during the COVID-19 pandemic, as well as sharing the potential benefits of using the KardiaMobile 6L as described in Table 2.

**Table 2: KardiaMobile 6L as a solution to ECG monitoring challenges**

<ul style="list-style-type: none"><li>• Takes 30 seconds to conduct</li><li>• Can stay in patient's room, limiting the risk to further spread disease</li><li>• Can be easily disinfected</li><li>• Does not require close contact by healthcare professionals</li><li>• Allows for more frequent ECG monitoring</li></ul>	<ul style="list-style-type: none"><li>• ECGs can be easily shared via PDF/Email/Text</li><li>• Potential for QT prolongation determination for immediate medication management</li><li>• Recording can be performed by anyone (ECG tech not needed).</li><li>• Decreases burden on healthcare system</li></ul>
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After presenting the challenges of the current healthcare environment and the potential benefits of using tools like our KardiaMobile 6L, AliveCor requested the FDA to allow for the following claims based on the FDA Emergency Use Authorization guidance:

- *KardiaMobile 6L can be used by healthcare professionals to monitor for QT prolongation in inpatients and outpatients receiving QT prolonging medications, including Hydroxychloroquine, Azithromycin, whether alone or in combination, for the treatment of COVID-19.*
- *KardiaMobile 6L can also be used in COVID-19 patients by healthcare professionals for the detection and monitoring of other cardiac arrhythmias, including atrial fibrillation, tachycardia, and bradycardia.*

### **III. FDA Correspondence**

On March 20, 2020, AliveCor was notified by the FDA as to the release of a new [guidance](#) for the use of non-invasive remote monitoring devices used to support patient monitoring during the COVID-19 pandemic and agreed to allow emergency use of AliveCor's KardiaMobile 6L to measure QTc in COVID-19 patients.

### **IV. Mayo Clinic Guidance to Manage QTc Prolonging and Torsadogenic Treatment of COVID-19**

On March 25, 2020, Mayo Clinic released a guidance to help healthcare providers mitigate the risk of disease transmission and QT prolongation and torsades de pointes in COVID-19 patients treated with hydroxychloroquine and/or azithromycin.<sup>4</sup> This guidance suggests that due to the risk of exposure of healthcare professionals to COVID-19 while retrieving a 12-lead ECG, alternatives such as the KardiaMobile 6L and other telemetry systems could generate accurate ECGs and thus be implemented to monitor the QTc.

### **V. Conclusion**

KardiaMobile 6L is an invaluable tool to obtain a 6-lead ECG in both inpatient and outpatient settings, providing clinicians with critical information to manage patients remotely. In light of the recent COVID-19 pandemic, the KardiaMobile 6L can be deployed to remotely monitor for QT prolongation, a potentially fatal side effect of the medicines currently being used for the treatment of COVID-19, to limit the exposure of healthcare professionals to infection and respond to the increasing demand of ECGs, as recommended by the Mayo Clinic's recent guidance. By using remote patient monitoring tools such as KardiaMobile 6L, we believe that the risk to healthcare professionals can be reduced while meeting the increased demand for ECGs to manage COVID-19 patients.