4. ACCESS AND INSTRUCTIONS TO DISPLAY REGULATORY INFORMATION

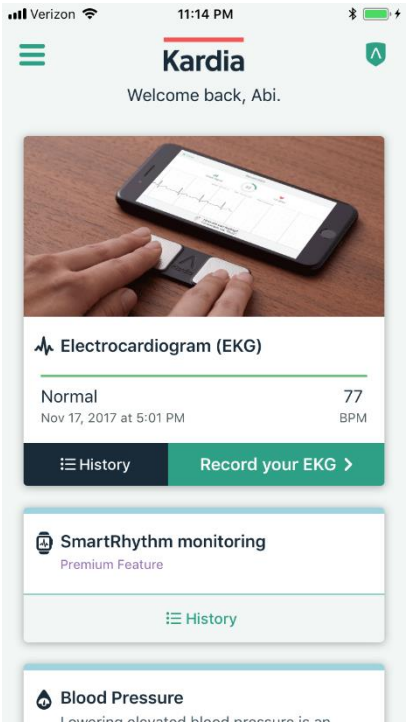
4.1 User Steps to Access Information

Users must be able to access the regulatory information without requiring special access codes or permissions, and in all cases the information must be accessible in no more than three steps from a product's main or home menu.

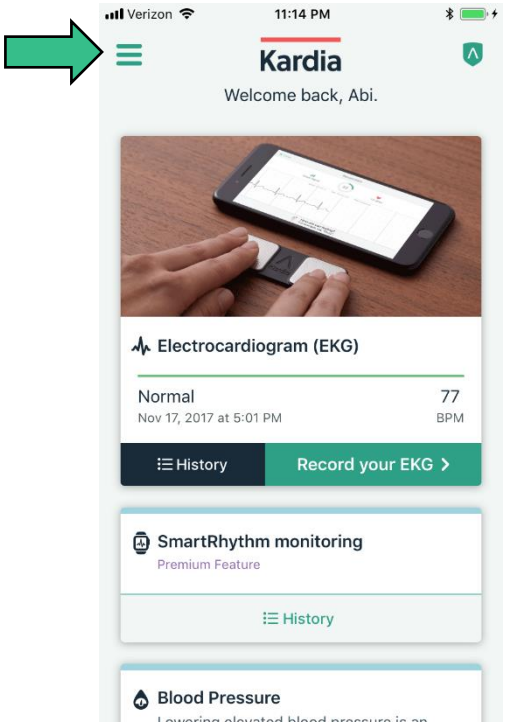
1) The KardiaMobile® (Model AC-019) device is intended to be used with Kardia app software installed on the user's smartphone or tablet. The device transmits electrocardiogram (ECG) data via Bluetooth Low Energy (BLE) to be displayed on the Kardia app. Shown below is an example of how the KardiaMobile device would be used and the ECG displayed on the user's smartphone.

2) In the Kardia app, regulatory information is accessible in the following way:

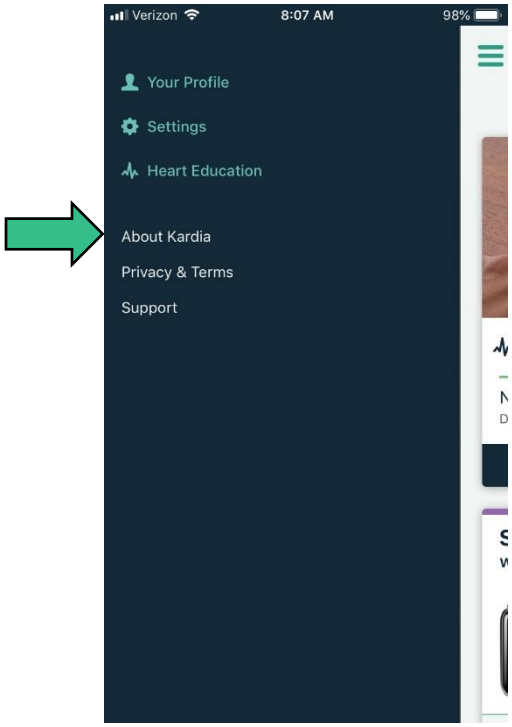
Starting from Main or Home Menu:



Step 1 – Accessing the submenu



Step 2 – Accessing “About Kardia”



Step 3 –Applicable regulatory information is displayed here

4.2 Products must not require special accessories or supplemental plug-ins (e.g., the installation of a SIM/USIM card) to access the information.

1) Access to regulatory information is provided without special codes, accessories, or permissions beyond the normal security protection to unlock the user's smartphone or tablet and login to their Kardia account.

2) Instructions will be provided in a product-related website (alivecor.com/quickstart) that will be printed on the products quick-start guide/pamphlet that is packaged with every new product and is available at the time of purchase.

4.3 Readability of Regulatory Information
The FCC ID will be displayed electronically in the Kardia app in a font size that is clearly legible without the aid of magnification.

4.4 Regulatory Information must be Secure

The Kardia app, including the regulatory information that it displays, is developed and implemented with HIPAA compliant policies and procedures and in consideration of the FDA guidance, entitled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", issued on October 18, 2018. Furthermore, AliveCor is ISO13485:2016 compliant design and change control procedures require robust validation and verification testing to ensure that the regulatory information correctly displayed for any new or updated products.

The regulatory information is available on the Kardia app locally (without the need for internet connection) and can be accessed end user in possession of the KardiaMobile device at any time.