

ATTORNEY GENERAL OF THE STATE OF NEW YORK

In the Matter of

Cardiio, Inc.

Assurance No.: 16-173

**ASSURANCE OF DISCONTINUANCE
UNDER EXECUTIVE LAW
SECTION 63, SUBDIVISION 15**

Pursuant to the provisions of Section 63(12) of the Executive Law, New York Education Law Section 6515, and Article 22-A of the General Business Law, Eric T. Schneiderman, Attorney General of the State of New York, caused an inquiry to be made into certain business practices of Cardiio, Inc.¹ Based upon that inquiry, the Office of the Attorney General (“the OAG”) has made the following findings, and Cardiio, Inc. has agreed to modify its business practices and comply with the following provisions of this Assurance of Discontinuance (“Assurance”).

I. BACKGROUND

1. The proliferation of smartphones and other mobile devices has created intense demand for mobile applications,² which consumers generally purchase through two online stores, Apple’s App Store (which offers versions for iPhones and compatible devices), and Google Play (which offers versions for Android phones and compatible devices).

¹ In this Assurance, “Cardiio, Inc.” shall mean Cardiio, Inc.’s owners, officers, agents, servants, employees, and those persons in active concert or participation with them.

² “Mobile application” is defined herein as a program designed to be or capable of being used on a smartphone or other mobile device.

2. Health-related mobile applications have become especially popular, with more than 165,000 currently available.³ The majority of these provide general medical reference and education or allow consumers to track their fitness or symptoms based on data they input themselves, and may promote health awareness. A narrower category of mobile applications (hereafter, “Health Measurement Apps”), however, purport to measure vital signs or other indicators of health using only a smartphone’s camera and sensors, without any external device. These Health Measurement Apps can be harmful to consumers if they provide inaccurate or misleading results.⁴ For example, these apps can provide false reassurance that a consumer is healthy, which might cause her to forego necessary medical treatment and thereby jeopardize her health. Conversely, Health Measurement Apps can incorrectly indicate a medical issue, causing a consumer to unnecessarily seek medical treatment – sometimes from a hospital emergency room.

II. THE OAG’S INVESTIGATION AND FINDINGS

3. Cardiio, Inc. is a Delaware corporation with its principal place of business at 45 Prospect Street, Cambridge, Massachusetts 02139.

4. The OAG’s Health Care Bureau received reports that consumers are downloading a Health Measurement App, Cardiio-Heart Rate Monitor + 7 Minute Workout Exercise Routine for Cardio Health and Fitness (“Cardiio-Heart Rate Monitor”)⁵, and using it to measure their

³ See <http://www.latimes.com/business/technology/la-me-mobile-health-safety-20160412-story.html>.

⁴ See, e.g., <http://www.imedicalapps.com/2015/02/apple-google-health-app-patients/>; <http://www.nejm.org/doi/full/10.1056/NEJMhle1403384>; http://www.slate.com/blogs/future_tense/2013/09/24/mhealth_fda_needs_to_regulate_digital_snake_oil.html; <http://www.motherjones.com/environment/2015/01/medical-apps-not-helping>; http://www.wired.com/2014/07/medical_apps/.

⁵ The App is available in a free version, a “Full Pro” version for \$6.99, and as part of “packs” that include other apps, such as “Target Heart Rate” for \$3.99, Life Expectancy Pack for \$2.99,

heart rate, or pulse. The OAG subsequently launched an investigation regarding Cardio-Heart Rate Monitor.

5. Cardio, Inc. has created, and offers Cardio-Heart Rate Monitor for sale to consumers around the world, including in New York State, through Apple’s App Store. Cardio also offers numerous in-app purchases through the app, such as a “calorie-burn monitor” that estimates how many calories a user has burned after exercise. Cardio-Heart Rate Monitor was first made available by Cardio, Inc. on August 2, 2012, and, according to the company, “turns your iPhone or iPad into a heart rate monitor!”⁶ Cardio-Heart Rate Monitor has been downloaded hundreds of thousands of times in the U.S. and has generated hundreds of thousands of dollars in gross revenue.

6. Heart rate, the number of times the heart beats per minute, is a vital sign that health care providers monitor in their patients.⁷ Healthy people typically have a resting heart rate between 60 and 100 beats per minute (“BPM”). A resting heart rate above or below this range can indicate a medical condition, such as heart disease.⁸ Clinicians measure heart rate using a heart rate monitor, which employs two types of technologies: electrocardiography (“ECG”), which measures the heart’s electrical activity, and photoplethysmography (“PPG”), which senses the rate of blood flow via light shined through the skin. Chest-strap heart rate monitors use ECG. A device called a pulse oximeter, which uses PPG to measure the level of oxygen in the blood, may also be used to measure heart rate.

Specific Heart Rate Pack for \$2.99, and Remove Ads/Rewards for \$1.99.

⁶ <https://itunes.apple.com/us/app/cardio-heart-rate-monitor/id542891434?mt=8>.

⁷ <https://medlineplus.gov/ency/article/002341.htm>.

⁸ <http://www.mayoclinic.org/healthy-lifestyle/fitness/expert-answers/heart-rate/faq-20057979>.

A. Cardio, Inc.'s Marketing of Cardio-Heart Rate Monitor

7. Cardio, Inc. instructs the consumer that to use Cardio-Heart Rate Monitor, she must place her index finger against the back camera lens and flashlight of a smart phone. The app then generates a number for her heart rate, as shown in this screenshot⁹:



As depicted above, the user sees an image of the head of a stethoscope and a graph with peaks and troughs while Cardio-Heart Rate Monitor purports to measure her heart rate, simulating a medical device. A user cannot tell whether the peaks and troughs are related to her actual heart rate, because there is no scale indicating what the graph shows. Cardio, Inc. also instructs users

⁹ <https://itunes.apple.com/us/app/cardio-heart-rate-monitor/id542891434?mt=8>.

of Cardio-Heart Rate Monitor that they can obtain a heart rate reading by simply holding their phone in front of their face (the “face mode”).¹⁰

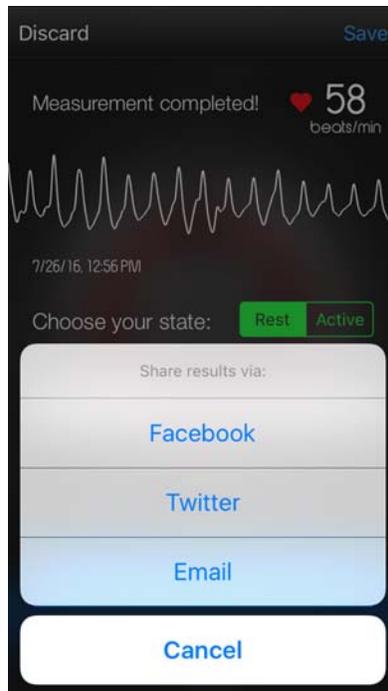
8. Cardio-Heart Rate Monitor creates a “Personal Dashboard” for the user based on the app’s measurements of her heart rate at rest, and before, and after, physical activity, as shown in this screenshot¹¹:



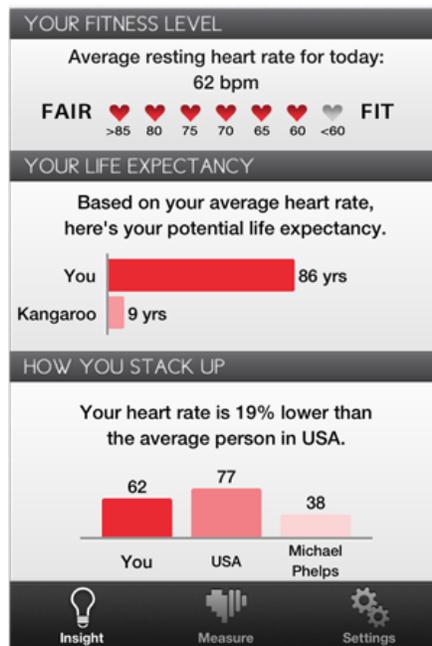
9. The Cardio-Heart Rate Monitor allows a user to save, and share via email and social media, the heart rate measurements that the app generates, and to indicate whether the measurement was obtained while the user was “[at] rest,” or “active,” as shown in this screenshot:

¹⁰ <https://itunes.apple.com/us/app/cardio-heart-rate-monitor/id542891434?mt=8>.

¹¹ <http://www.cardiio.com/>.



10. Cardio-Heart Rate Monitor also purports to estimate users' potential life expectancy, based on its calculation of average heart rate, age, and gender, as shown in this screenshot¹²:



¹² <http://www.cardiio.com/>.

11. Cardiio, Inc. placed Cardiio-Heart Rate Monitor in the “Health & Fitness” category in Apple’s App Store, and in the listing it created for the App Store, makes the following claims about Cardiio-Heart Rate Monitor¹³:

- a. “The Cardiio app turns your iPhone or iPad into a heart rate monitor!”
- b. “Cardiio’s technology is based on cutting-edge research and science conducted at the MIT Media Lab. The measurement principles are the same as clinical pulse oximeters.”
- c. “Studies have shown that our heart rate measurements are within 3 bpm of a clinical pulse oximeter when performed at rest in a well-lit environment.”

12. Cardiio, Inc., on its website, makes the following claims about Cardiio-Heart Rate Monitor¹⁴:

- a. “Simply hold your phone in front of you and get your heart rate accurately measured in seconds.”
- b. “Simply Magical. Touch-free Heart Rate Monitoring. Cardiio works by simply having you look straight into the front camera of your iPhone/iPad to measure your heart rate from a distance. No uncomfortable chest straps needed. You don’t even have to touch the camera! It’s the whole new way to monitor your heart and track your health.”
- c. “Every Beat Counts. Create Your Personal Dashboard. Scan your heart rate when you wake up, after a run or yoga, or before a meeting with your boss! See how your heart rate changes over time through beautiful visualizations of your data.”
- d. “Gain Insight. Your Resting Heart Rate is an Important Indicator of General Wellness, Fitness and Longevity. Cardiio analyzes your heart rate data to provide you with a fitness level rating and also estimates your potential life expectancy. Set personal goals for your resting heart rate and see how you stack up against others!”
- e. “How Cardiio Works. Cardiio is powered by cutting-edge research and science conducted at the MIT Media Lab. Every time your heart beats, more blood is pumped into your face. This slight increase in blood volume causes more light to be absorbed, and hence less light is reflected from your face. Cardiio uses your

¹³ <https://itunes.apple.com/us/app/cardiio-heart-rate-monitor/id542891434?mt=8>.

¹⁴ <http://www.cardiio.com/>.

camera to track these tiny changes in reflected light that are not visible to the human eye and calculate your heart beat! Measurement accuracy is within 3 beats/min of a clinical pulse oximeter when performed at rest in a well-lit environment.”

13. The net impression that Cardiio, Inc. conveyed to the consumer about Cardiio-Heart Rate Monitor is that the app would accurately measure and monitor her heart rate after she has engaged in strenuous physical activity, such as running, whatever her physical condition. The name of the app and the statements and images referenced in Paragraphs 7 through 12 above, taken together, strongly suggested that the app would accurately measure heart rate after strenuous exercise, which is a vital sign, with the accuracy of a medical device.

14. Cardiio, Inc. made the above-noted post-exercise claims about Cardiio-Heart Rate Monitor without providing sufficient evidence substantiating that the app accurately measures the heart rate of individuals who have engaged in strenuous exercise such as running, despite specifically promoting its use in such conditions.¹⁵

15. Moreover, Cardiio, Inc.’s assertions that Cardiio-Heart Rate Monitor can calculate a user’s potential life expectancy and estimate how the user “stacks up” against “the average person” in the USA did not contain sufficient disclosures that these calculations were hypothetical and estimates not intended to measure accurately life expectancy.

16. The United States Food and Drug Administration (“FDA”), regulates cardiac monitors used to measure heart rate as Class II medical devices¹⁶, which means they are “higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device’s safety and effectiveness.”¹⁷

¹⁵ Cardiio, Inc. did provide sufficient evidence regarding the accuracy of the Cardiio-Heart Rate Monitor’s heart rate measurements when conducted at rest and in a well-lit environment.

¹⁶ See 21 C.F.R. § 870.2300.

¹⁷ <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm>.

17. Cardio-Heart Rate Monitor can potentially harm consumers if it provides inaccurate or misleading results, because accurate heart rate readings are critical to the health of consumers whose medical conditions require them to maintain (or not exceed) a certain heart rate. Consumers could jeopardize their health by relying on inaccurate heart rate readings and potentially reaching dangerous heart rates. For example, if Cardio-Heart Rate Monitor provides a consumer with a reading of 82 BPM when the consumer's actual heart rate is much higher, the consumer could exceed the maximum target heart rate for his or her age during exercise, and thereby jeopardize his or her health. A person's maximum heart rate is generally calculated as 220 BPM minus a person's age.¹⁸ A person who exceeds 85% of her maximum heart rate (her "maximum target") during vigorous exercise is at risk of ventricular tachycardia (rapid heart rhythm in the bottom chambers of the heart) and ST-segment depression (abnormalities in ECG), conditions which can indicate increased risk of cardiac mortality.¹⁹ To illustrate, for a 40-year-old person, her maximum heart rate is 180 BPM, and her maximum target is 153 BPM.

18. Numerous reviews indicate that Cardio-Heart Rate Monitor is being used by people after exercise, and by people with serious medical conditions, such as rapid heart beat, atrial fibrillation, tachycardia, and arrhythmia requiring a pacemaker. Some of these reviews indicate that Cardio-Heart Rate Monitor's heart rate readings may be inaccurate. For example, in December 2015, a user stated in a review of the app: "Recently my son ha[d] a bout of bronchitis and his heart beat really fast. I tried to listen to his heart beat manually then

¹⁸ See <http://www.mayoclinic.org/healthy-lifestyle/fitness/in-depth/exercise-intensity/art-20046887?pg=2>.

¹⁹ See Atwal, Porter, & MacDonald, *Cardiovascular effects of strenuous exercise in adult recreational hockey: the Hockey Heart Study*. 166 *Canadian Medical Association J.* 303-307 (Feb. 2002); Koplan & Stevenson, *Ventricular tachycardia and sudden cardiac death*. 84 *Mayo Clinic Proceedings* 289-97 (Mar. 2009); Birnbaum et al., *Prognostic significance of precordial ST segment depression on admission electrocardiogram in patients with inferior wall myocardial infarction*. 28 *J. Am. Coll. Cardiology* 313-18 (Aug. 1996).

remembered I had this app so I busted it out but boy was It way off. Showing 45 bpm when my son was over 100.”

19. As a result of the OAG’s investigation, Cardiio, Inc. provided to the OAG sufficient evidence reflecting testing of Cardiio-Heart Rate Monitor. Such testing was supervised by individuals who possess Ph.D.’s in Electrical and Medical Engineering, and Biomedical Engineering. One of these individuals is a signatory to the AOD, and attests that Cardiio-Heart Rate Monitor provides accurate heart rate measurements both at rest and after exercise.

20. As a result of the OAG’s investigation, Cardiio, Inc. disclosed clearly and prominently²⁰, on its website and in the App Store listing for Cardiio-Heart Rate Monitor:

- a. The following statement, which is also disclosed in a pop-up message that appears upon first use of the app:

WARNING: NOT FOR MEDICAL USE

“If knowing your pulse rate is critical to your health, you need to have your pulse taken by a medical professional. Cardiio is not intended to diagnose, prevent or treat any condition, or to be a substitute for professional medical care. Measurements and statistics are intended for informational and educational purposes only, to support general health and wellness. The Cardiio app has not been tested with individuals with health conditions, is not a clinical pulse oximeter and has not been cleared or approved by the U.S. Food and Drug Administration.

- b. Cardiio’s technology is based on technology licensed from MIT and originally developed at the MIT Media Lab. MIT has not endorsed Cardiio-Heart Rate Monitor or Cardiio, Inc.

²⁰ “Clearly and prominently,” as used in this Assurance, means, in textual communications (*e.g.*, printed publications or words displayed on the screen of a computer or mobile device), that the required disclosures are of a type, size, and location sufficiently noticeable for an ordinary consumer to read and comprehend them, in print that contrasts highly with the background on which they appear. The required disclosures must: (1) be presented in an understandable language and syntax; and (2) include nothing contrary to, inconsistent with, or in mitigation of any statement contained within the disclosure or within any document linked to or referenced therein.

- c. Regarding the “potential life expectancy” feature of Cardio-Heart Rate Monitor, the following statement, which is also disclosed in the app each time the feature is used:

This is a hypothetical calculation that is purely an estimate and not intended to measure accurately life expectancy.

Cardio, Inc. will disclose in an “FAQ” page on Cardio-Heart Rate Monitor that the “potential life expectancy” feature of the app is based on the user’s average heart rate as measured by the app, and gender and age as entered by the user.

B. Cardio, Inc.’s Privacy Practices

21. Cardio, Inc. maintains a Privacy Policy that states how the company handles users’ personal information, including heart rate readings, generated by Cardio-Heart Rate Monitor (“Cardio, Inc.’s Privacy Policy,” the “Privacy Policy,” or the “Policy”). Prior to the OAG’s investigation, Cardio, Inc. did not require that users expressly consent to the Policy. Rather, Cardio, Inc. deemed a consumer to have consented to the Policy by providing data such as age, gender, weight, and existing heart-related conditions, and “waveforms related to [users’] heart signal obtaining from the processing of the camera input.” This default consent did not ensure that potential users understood Cardio, Inc.’s Privacy Policy, because they may never have seen it.

22. Cardio, Inc.’s Privacy Policy states that the company collects various types of data from users of Cardio-Heart Rate Monitor, including age, gender, weight, and existing heart-related conditions,” and “waveforms related to [users’] heart signal obtaining from the processing of the camera input.” Though not stated in the Privacy Policy, Cardio had the right to collect information regarding users’ GPS location with express consent of users, which, when combined with other information about a user, may be personally identifiable information.

23. Cardio, Inc.’s Privacy Policy also states that it may disclose to its affiliates, agents and business partners “aggregated” data compiled from the information that it collects

from users. Although Cardiio, Inc. states that this data does not identify users personally, it did not disclose to consumers the risk that third parties who receive such data from Cardiio, Inc. may reidentify specific users.²¹

24. Cardiio, Inc.'s Privacy Policy stated that it may disclose users' personal information to third parties if it believed in good faith that disclosure of users' personal data was "reasonably necessary to protect the property or rights of Cardiio, third parties or the public at large." This conferred virtually unlimited discretion on Cardiio, Inc. in disclosing users' personal information.

25. Cardiio, Inc. did not disclose to users of Cardiio-Heart Rate Monitor that the personal health information collected and stored by Cardiio, Inc., and subsequently shared by the user via Cardiio-Heart Rate Monitor, may not be protected under the Health Insurance Portability and Accountability Act ("HIPAA").

26. Cardiio, Inc. has represented to the OAG that it has not disclosed any personally identifiable user information to any third parties.

27. As a result of the OAG's investigation, Cardiio, Inc. modified its Privacy Policy for Cardiio-Heart Rate Monitor to state clearly and prominently the following:

- a. Cardiio, Inc. secures express consent to its Privacy Policy from users of its mobile applications, via a message that requires users to physically scroll through the entire Policy and, before using the Cardiio-Heart Rate Monitor app, click on a button that states: "I have read and agree to the Privacy Policy for Cardiio-Heart Rate Monitor." This applies to any revisions to the Privacy Policy.
- b. Cardiio deems personally identifiable user information confidential and does not disclose such information without the express informed consent of the user. Such consent shall be secured through an express action by the consumer such as

²¹ See Paul Ohm, Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization, 57 UCLA Law Rev. 1701 (2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1450006; Sweeney L., Only You, Your Doctor, and Many Others May Know, Technology Science, September 29, 2015, available at <http://techscience.org/a/2015092903>.

clicking a check-box, providing an electronic signature, or other substantially similar method, after clear and conspicuous disclosure immediately above such check-box or electronic signature, indicating that the consumer is agreeing to the disclosure of his or her information by Cardiio, Inc. A pre-checked box shall not be considered evidence of consent. Cardiio shall not disclose personally identifiable user information to any person or organization not specifically authorized by the individual user.

- c. Cardiio, Inc. does not collect or disclose information regarding users' GPS location without express consent of users.
- d. Cardiio, Inc. discloses to users the standard of care employed to protect personally identifiable user information.
- e. Cardiio, Inc. may disclose personally identifiable user information in response to lawful requests from federal, state, local, or foreign law and civil enforcement agencies.
- f. Cardiio, Inc. may disclose with its affiliates, agents and business partners "aggregated" data compiled from the information that it collects from users. Although this data does not identify users personally, there is a risk that third parties who receive such data from Cardiio, Inc. may reidentify specific users.
- g. Personal health information collected by Cardiio, Inc., and subsequently shared by the user via Cardiio-Heart Rate Monitor, may not be protected under the Health Insurance Portability and Accountability Act ("HIPAA").

For purposes of this Assurance, the words "disclose" or "discloses" do not include Cardiio, Inc. allowing third-party service providers (such as database hosting companies, email service providers, and other similar service providers) limited access to personally identifiable user information in the scope of their work to help Cardiio, Inc. provide and maintain its services and business.

III. RELEVANT NEW YORK STATE LAW

28. The New York State Executive Law prohibits "illegal or fraudulent acts" in the conduct of any business, trade or commerce, and allows the OAG to institute a special proceeding for restitution, damages, and/or injunctive relief against any party which has committed such acts. N.Y. Exec. Law § 63(12).

29. The New York General Business Law prohibits “deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service” in New York State, as well as “false advertising in the conduct of any business,” and authorizes the OAG to enjoin any such practices. N.Y. Gen. Bus. Law §§ 349 and 350.

30. Marketing a Health Measurement App without substantiation that it accurately measures what it purports to measure, and without fully and clearly disclosing privacy practices, constitute deceptive business practices in violation of New York Executive Law § 63(12) and General Business Law §§ 349 and 350.

NOW, WHEREAS, Cardio, Inc. neither admits nor denies the Attorney General’s findings in Paragraphs 4 through 18 and 21 through 25 above; and

WHEREAS, New York laws prohibiting deceptive business practices and misleading advertising confer important consumer and public health protections; and

WHEREAS, Cardio, Inc. has cooperated with the OAG’s investigation; and

WHEREAS, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and to discontinue his investigation; and

WHEREAS, the parties each believe that the obligations imposed by this Assurance are prudent and appropriate; and

WHEREAS, the Attorney General has determined that this Assurance is in the public interest.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the parties that:

IV. PROSPECTIVE RELIEF

A. Documentation of Substantiation

31. If Cardio, Inc. makes any material change to its claims concerning the functionality of Cardio-Heart Rate Monitor, it must perform testing to substantiate any such

claims. The testing must be performed by researchers qualified by training and experience to conduct such testing. Cardiio, Inc. shall secure and preserve all data, analyses, and documents regarding such testing, and make them available to the OAG upon request.

B. Changes to Cardiio-Heart Rate Monitor

32. Cardiio, Inc. shall maintain the changes to Cardiio-Heart Rate Monitor described above in Paragraph 20.

33. Cardiio, Inc. shall not make, or assist others in making, expressly or by implication, including through the use of the Cardiio-Heart Rate Monitor name, endorsement, depiction, or illustration, any false or misleading representation or claim regarding the health benefits or efficacy of Cardiio-Heart Rate Monitor.

C. Privacy Protections

34. Cardiio, Inc. shall maintain the changes to its Privacy Policy for Cardiio-Heart Rate Monitor described above in Paragraph 27.

35. Cardiio, Inc. shall not misrepresent in any manner, expressly or by implication, the extent to which it maintains the privacy or security of user information,²² including but not limited to:

- a. Its collection or disclosure of any personally identifiable user information collected with Cardiio-Heart Rate Monitor, including but not limited to users' GPS location and device identifier; and
- b. The extent to which Cardiio, Inc. makes or has made personally identifiable user information collected with Cardiio-Heart Rate Monitor accessible to third parties.

36. Prior to sharing any de-identified user information collected with Cardiio-Heart Rate Monitor with third parties, Cardiio, Inc., shall, in writing, secure the express written

²² "User information," as used in this Assurance, means any information collected from a user.

agreement of such third parties that they will not attempt to re-identify the information to any particular individual.

37. To protect the security of personally identifiable user information, Cardio, Inc. shall:

- a. Establish and implement reasonable security policies and procedures designed to protect personally identifiable user information collected with Cardio-Heart Rate Monitor. Such policies and procedures, which shall be documented in writing, shall be appropriate to the nature and scope of Cardio, Inc.'s activities and the sensitivity of the covered information.
- b. At least bi-annually, review its existing security policies and procedures designed to protect personally identifiable user information collected with Cardio-Heart Rate Monitor, and update such policies and procedures as necessary to maintain reasonable security.

V. MONETARY PENALTIES, FEES and/or COSTS

38. Within thirty (30) days of the Effective Date, Cardio, Inc. shall pay \$5,000 to the OAG for penalties, fees and/or costs of the Attorney General's investigation.

39. Such sum shall be payable by check to "State of New York Department of Law."

VI. LIQUIDATED DAMAGES

40. If Cardio, Inc. violates any provision of this Assurance, the OAG may elect to demand that Cardio, Inc. pay liquidated damages of \$5,000 per violation for such non-compliance. Before liquidated damages may be imposed, the OAG shall give Cardio, Inc. written notice that Cardio, Inc. may be subject to liquidated damages under this Paragraph. In the event that Cardio, Inc. does not cure the violation within ten (10) days of receipt of the OAG's written notice, the OAG may impose liquidated damages pursuant to this Paragraph. The damages period shall commence on the date that Cardio, Inc. receives the OAG's written notice and end on the date that Cardio, Inc. cures the violation or provides the requested information.

VII. GENERAL PROVISIONS

41. Compliance: Cardiio, Inc. shall submit to the OAG, within sixty (60) days of the Effective Date, a detailed letter certifying and setting forth its compliance with the terms of this Assurance.

42. Cardiio, Inc.'s Representations: The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by Cardiio, Inc. and its counsel and the OAG's own factual investigation as set forth in the above Findings. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

43. Communications: All communications, reports, correspondence, and payments that Cardiio, Inc. submits to the OAG concerning this Assurance or any related issues are to be sent to the attention of the person identified below:

Michael D. Reisman, Esq.
Assistant Attorney General
Health Care Bureau
Office of the New York State Attorney General
120 Broadway
New York, New York 10271

44. Receipt by the OAG of materials referenced in this Assurance, with or without comment, shall not be deemed or construed as approval by the OAG of any of the materials, and Cardiio, Inc. shall not make any representations to the contrary.

45. All notices, correspondence, and requests to Cardiio, Inc. shall be directed as follows:

Ming-Zher Poh
Cardiio, Inc.
45 Prospect Street
Cambridge, MA 02139

46. Valid Grounds and Waiver: Cardio, Inc. hereby accepts the terms and conditions of this Assurance and waives any rights to challenge it in a proceeding under Article 78 of the Civil Practice Law and Rules or in any other action or proceeding.

47. No Deprivation of the Public's Rights: Nothing herein shall be construed to deprive any member or other person or entity of any private right under law or equity.

48. No Blanket Approval by the Attorney General of Cardio, Inc.'s Practices: Acceptance of this Assurance by the OAG shall not be deemed or construed as approval by the OAG of any of Cardio, Inc.'s acts or practices, or those of its agents or assigns, and none of them shall make any representation to the contrary.

49. Monitoring by the OAG: To the extent not already provided under this Assurance, Cardio, Inc. shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance. Cardio, Inc. may request an extension of particular deadlines under this Assurance, but OAG need not grant any such request. This Assurance does not in any way limit the OAG's right to obtain, by subpoena or by any other means permitted by law, documents, testimony, or other information.

50. No Limitation on the Attorney General's Authority: Nothing in this Assurance in any way limits the OAG's ability to investigate or take other action with respect to any non-compliance at any time by Cardio, Inc. with respect to this Assurance, or Cardio, Inc.'s non-compliance with any applicable law with respect to any matters.

51. No Undercutting of Assurance: Cardio, Inc. shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects Cardio, Inc.'s: (a) testimonial obligations, or (b) right to take legal or factual positions in defense of litigation or

other legal proceedings to which the OAG is not a party. This Assurance is not intended for use by any third party in any other proceeding.

52. Under Executive Law Section 63(15), evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable law in any action or proceeding thereafter commenced by the OAG.

53. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

54. If a court of competent jurisdiction determines that Cardiio, Inc. has breached this Assurance, Cardiio, Inc. shall pay to the OAG the cost, if any, of such determination and of enforcing this Assurance, including, without limitation, legal fees, expenses, and court costs.

55. In the event the Assurance is voided or breached, Cardiio, Inc. expressly agrees and acknowledges that this Assurance shall in no way bar or otherwise preclude the OAG from commencing, conducting or prosecuting any investigation, action or proceeding, however denominated, related to the Assurance, against Cardiio, Inc., or from using in any way any statements, documents or other materials produced or provided by Cardiio, Inc. prior to or after the date of this Assurance.

56. None of the parties shall be considered to be the drafter of this Assurance or any provision for the purpose of any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter hereof. This Assurance was drafted with substantial input by all parties and their counsel, and no reliance was placed on any representation other than those contained in this Assurance.

57. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, in the sole

discretion of the OAG such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

58. This Assurance contains an entire, complete, and integrated statement of each and every term and provision agreed to by and among the parties, and the Assurance is not subject to any condition not provided for herein. This Assurance supersedes any prior agreements or understandings, whether written or oral, between and among the OAG and Cardio, Inc. regarding the subject matter of this Assurance.

59. This Assurance may not be amended or modified except in an instrument in writing signed on behalf of all the parties to this Assurance.

60. The division of this Assurance into sections and subsections and the use of captions and headings in connection herewith are solely for convenience and shall have no legal effect in construing the provisions of this Assurance.

61. Binding Effect: This Assurance is binding on and inures to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than the OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without prior written consent of the OAG. "Successors" includes any entity which acquires the assets of Cardio, Inc. or otherwise assumes some or all of Cardio, Inc.'s current or future business.

62. Effective Date: This Assurance is effective on the date that it is signed by the Attorney General or his authorized representative (the "Effective Date"), and the document may be executed in counterparts, which shall all be deemed an original for all purposes.

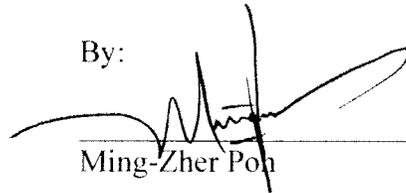
AGREED TO BY THE PARTIES:

Dated: *Cambridge, MA*

January 14, 2017

Cardio, Inc.

By:


Ming-Zher Poh

Dated: New York, New York

January 23, 2017

ERIC T. SCHNEIDERMAN

Attorney General of the State of New York

LISA LANDAU

Bureau Chief

Health Care Bureau

By:



MICHAEL D. REISMAN

Assistant Attorney General

Health Care Bureau