	Al .		
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10			
11	UNITED STATES DISTRICT COURT		
12	NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION		
13			
	FEDERAL TRADE COMMISSION,		
14	Plaintiff,	Case No. <u>3:17-cv-314-LB</u>	
15	v.	STIPULATED FINAL ORDER FOR	
16	BREATHOMETER, INC., a corporation,	PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF	
17	-	•	
18	and		
19	CHARLES MICHAEL YIM, individually and as		
20	Chief Executive Officer of Breathometer, Inc.,		
21			
22	Defendants.		
23			
24	Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint		
	for Permanent Injunction and Other Equitable Relief ("Complaint") in this matter, pursuant to		
25	Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The		
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27	Commission and Defendants stipulate to the entry of this Stipulated Final Order for Permanent		
28	Injunction and Other Equitable Relief ("Order") to resolve all matters in dispute in this action Page 1 of 20		
	rage 1 01 2	Case No. 3:17-cv-314-LB Stipulated Final Judgment and Order	

this Order, whether acting directly or indirectly, in connection with the advertising, labeling, Page 3 of 20

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promotion, offering for sale, sale, or distribution of any Breathalyzer Device are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that the Breathalyzer Device:

- A. Detects consumers' blood alcohol levels; or
- B. Is comparable or superior to other Breathalyzer Devices or to devices for blood or breath alcohol concentration detection used by law enforcement, unless the representation is non-misleading and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means testing that demonstrates that the manufactured device meets the accuracy specifications set for evidential breath alcohol testers that have been tested and approved by the Department of Transportation as laid out in *Highway Safety Programs; Model Specifications for Devices to Measure Breath Alcohol*, 58 FR 48705, Sept. 17, 1993, that is, repeated testing (at least 10 measurements per condition, at three decimal places) must demonstrate accuracy to within \pm 0.005 BAC, with a standard deviation within \pm 0.0042, at 0.020, 0.040, 0.080; and to within \pm 0.008 BAC, with a standard deviation within \pm 0.0042, at 0.160 BAC. Tests must demonstrate the same levels of accuracy after the device has "soaked" in a temperature control chamber of 20° C (\pm 1° C) for one hour, and also at 30° C (\pm 1° C) for one hour. Further, to ensure stability of readings, the tests for accuracy at 0.080 must be repeated thirty days after the initial tests, to ensure that the device holds calibration.

Unless otherwise specified, all such tests must be performed in the absence of drafts and at prevailing normal laboratory temperature, humidity, and barometric pressure. Ethyl alcohol must be used to prepare the test samples. A Department of Transportation approved calibrating unit of the type that uses aqueous alcohol solutions thermostated at 34° C and a ratio of headspace concentration of 0.000393 must be used to provide the BAC samples. The calibrating unit must be capable of delivering 10 complete vapor samples with alcohol depletion of not more than 1%.

Tests must further demonstrate that the product does not suffer from acetone interference at .020 BAC under the following two conditions: 70 microliters acetone per 500 ml solution, and 115 microliters acetone per 500 ml solution.

In addition, repeated tests (at least 10 measurements) must show accuracy within \pm .005 BAC at 0.000, with no single result greater than 0.005 BAC. These tests must be conducted on one or more persons who have not consumed alcohol in the past 48 hours nor smoked within the past 20 minutes, using his or own breath.

II. PROHIBITED REPRESENTATIONS: OTHER DEVICE CLAIMS

IT IS FURTHER ORDERED that the Individual Defendant, his agents, employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation about the absolute or comparative safety, health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific Page 5 of 20

evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision of this Order entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission.

III. PROHIBITED MISREPRESENTATIONS REGARDING TESTS

IT IS FURTHER ORDERED that the Individual Defendant, his agents, employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration:

A. That the performance or benefits of the Covered Product are scientifically or Page 6 of 20

clinically proven or otherwise established;

- B. That the performance or benefits of the Covered Product have been proven by government lab-grade testing; or
- C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

IV. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study

("test") upon which the Individual Defendant relies to substantiate any claim covered by the

Provision of this Order entitled Prohibited Representations: Other Device Claims, the

Individual Defendant must secure and preserve all underlying or supporting data and documents
generally accepted by experts in the field as relevant to an assessment of the test, including:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on

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any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts, between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) Individual Defendant; (2) his officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with him; (4) any person or entity affiliated with or acting on his behalf; (5) any supplier of any component contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product. For the purposes of this Provision, "reliably reported," for a human clinical test or study ("test"), means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Individual Defendant, he must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to his organization's size and complexity, the nature and scope of his activities, and the sensitivity of the personal information collected from or about the participants.

V. PROHIBITED CONDUCT REGARDING THE BREATHOMETER APP

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from re-enabling the Breathometer Page 8 of 20

app's breathalyzer functions, which were disabled prior to entry of this Order.

VI. CONSUMER NOTICE

IT IS FURTHER ORDERED that Defendants must provide adequate and timely notice of this Order to owners of both Original and Breeze by email and on the Breathometer website homepage.

- A. For the purposes of this paragraph, adequate and timely notice means:
- 1. An email, sent within five days of entry of this Order, in the exact wording and format set forth in Attachment A, with the subject line "Your Breathometer Breathalyzer Refund," and without any other materials accompanying the email; and
- 2. A prominent notice on the Breathometer website homepage, posted within two days of entry of this Order, and remaining on the homepage until 90 days after entry of this Order, in the exact wording set forth in Attachment B, in a location that does not require the website visitor to scroll to see the notice, even if accessing the website from a mobile phone or tablet.
- B. The notices must provide the link to an online Claim Form containing the exact wording set forth in Attachment C, in an easily legible format.

VII. CONSUMER REDRESS

IT IS FURTHER ORDERED that Defendants must provide full refunds to owners of Breathometer Brand Breathalyzer Devices as follows:

- A. Refunds must be for the full amount claimed by the owner in the online Claim Form (set forth in Attachment C), unless Defendants have already fully refunded such owner.
- B. Defendants must provide refunds to any owner who submits the online Claim Form within 125 days after entry of this Order; such refund must be provided within 90 days of Defendants' receipt of a completed Claim Form from an owner.
 - C. Defendants must not require owners to submit any documentation other than the

completed Claim Form nor impose any condition on owners seeking refunds.

- D. Within 230 days of entry of this Order, Defendants must provide the FTC with records sufficient to show the dates, times, and form of notifications to each owner, the refunds requested and paid to each such owner, any refund requests that were denied due to a prior full refund, and any refunds paid by Defendants to individual consumers after June 9, 2016.
- E. In the event that refunds paid to owners pursuant to this Provision total less than \$1 million, Defendants, jointly and severally, must pay to the Commission, within 235 days of entry of this Order, the difference between the refunds paid and \$1 million; *provided that*, cash refunds paid by Defendants to individual consumers after June 9, 2016 will be considered to have been made pursuant to this Provision.
- F. Defendants relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.
- G. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this paragraph.
- H. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to Page 10 of 20

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nondischargeability complaint in any bankruptcy case.

- I. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purpose.
- J. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants must immediately furnish to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. §7701.

CUSTOMER INFORMATION VIII.

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, are permanently restrained and enjoined from failing to provide sufficient customer information to enable the Commission to efficiently monitor consumer refunds as prescribed by the Provision of this Order entitled Consumer Redress. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

IX. ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendants obtain acknowledgments of receipt of this Order:

- Each Defendant, within 7 days of entry of this Order, must submit to the A. Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.
 - B. For 3 years after entry of this Order, for any business that the Individual Page 11 of 20

Defendant, individually or collectively with the Corporate Defendant, is the majority owner or controls directly or indirectly, and each Corporate Defendant, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X. COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission:

- A. Within one year after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:
- 1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which the Individual Defendant must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Defendant is in compliance with each Provision of this Order; and (e) provide a copy of each Order Acknowledgment obtained Page 12 of 20

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pursuant to this Order, unless previously submitted to the Commission.

- 2. Additionally, the Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which the Individual Defendant performs services whether as an employee or otherwise and any entity in which the Individual Defendant has direct or indirect control; and (c) describe in detail the Individual Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.
- For 10 years after entry of this Order, each Defendant must submit a compliance B. notice, sworn under penalty of perjury, within 30 days of any change in the following:
- 1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of the Corporate Defendant or any entity that such Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
- 2. Additionally, the Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has direct or indirect control, and identify the name, physical address, and any Internet address of the business or entity.
- C. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant Page 13 of 20

within 14 days of its filing.

- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: FTC v. Breathometer, Inc., et al.

XI. RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, the Corporate Defendant and the Individual Defendant for any business that he, individually or collectively with the Corporate Defendant, is a majority owner or controls directly or indirectly, must create and retain the following records:

- A. Accounting records showing the revenues from all goods or services sold;
- B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- C. Records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;
 - D. All records necessary to demonstrate full compliance with each Provision of this Page 14 of 20

Order, including all submissions to the Commission; and

E. A copy of each unique advertisement or other marketing material.

XII. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order, including any failure to transfer any assets as required by this Order:

- A. Within 14 days of receipt of a written request from a representative of the Commission, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.
- B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.
- C. The Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.
- D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning the Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. §1681b(a)(1).

RETENTION OF JURISDICTION XIII. IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for 2 3 purposes of construction, modification, and enforcement of this Order. 4 5 6 UNITED STATES DISTRICT JUDGE 7 8 SO STIPULATED AND AGREED: 9 FOR DEFENDANT BREATHOMETER: FOR PLAINTIFF: 10 11 Charles Michael Yim, Chief Executive Office JANET M. EVANS 12 of Breathometer, Inc. DC Bar No. 358467 **ELIZABETH JONES SANGER** 13 FOR DEFENDANT CHARLES MICHAEL WI Bar No. 1080449 YIM: 14 Attorneys for Plaintiff FEDERAL TRADE COMMISSION 15 600 Pennsylvania Avenue, NW Mail Drop CC-10528 16 Charles Migh hel Yim Washington, D.C. 20580 Tel.: 202-326-2125, -2757 17 ATTORNEYS FOR DEFENDANTS: Fax: 202-326-3259 18 Email: jevans@ftc.gov; esanger@ftc.gov 19 20 DC Bar No. 176123 JENNIFER M. THOMAS 21 DC Bar No. 987518 22 Hyman, Phelps & McNamara, P.C. 700 13th Street, NW 23 Washington, DC 20005 Tel.: 202-737-4580, -4280 24 Fax: 202-737-9329 Email: jflcder@hpm.com; jthomas@hpm.com 25 COUNSEL FOR BREATHOMETER, INC. 26 27 28 JOHN GRAUBERT Case No. 3:17-cv-314-LB Page 16 of 20

Stipulated Final Judgment and Order

DC Bar No. 370670 **BRANDON MYERS** DC Bar No. 1023569 Covington & Burling LLP One CityCenter 850 Tenth Street, NW Washington, DC 20001 Tel.: 202-662-5938, -5132 Fax: 202-778-5938 Email: jgraubert@cov.com; bmyers@cov.com COUNSEL FOR MR. YIM

1	ATTACHMENT A [EMAIL NOTICE]			
2 3	SUBJECT LINE: Your Breathometer Breathalyzer Refund			
4	[EMAIL CONTENT]			
5				
	Your Breathometer breathalyzer refund			
6 7	Dear Breathometer customer:			
8	Your Breathometer breathalyzer and the accompanying app have been disabled because of a potentially serious safety issue. The breathalyzer has been shown in some cases to falsely report a low blood alcohol concentration (BAC) reading, even when it's unsafe for the user to drive.			
9 10				
10	You are receiving this notice as a result of a lawsuit alleging deceptive advertising filed against			
12	us by the Federal Trade Commission, the nation's consumer protection agency. We have disabled the Breathometer app and have agreed to offer refunds to Breathometer Original and Breathometer Breeze customers.			
13				
14 15	Visit [clickable URL, linked to Attachment C, a page on the Breathometer website] to file for your refund. You must submit your refund request no later than [insert date 90 days after the date notice was provided pursuant to Provision VI.A.1. of the Order]. If you have questions, please contact us [800-xxx-xxxx] or BAC@breathometer.com.			
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18	Sincerely,			
19	Team Breathometer			
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ATTACHMENT B [NOTICE ON BREATHOMETER WEBSITE HOMEPAGE]

Important Refund Notice for Original and Breeze Customers

[clickable button, linked to Attachment C, a page on the Breathometer website]

Page 19 of 20

ATTACHMENT C [REFUND CLAIM VIA FILLABLE FORM WEBPAGE]

Breathometer Original and Breathometer Breeze REFUND CLAIM FORM

FTC v. Breathometer, Inc. and Others

Breathometer Original and Breeze customers are entitled to a refund as a result of a
settlement in a lawsuit filed against us by the Federal Trade Commission, the nation's
consumer protection agency.

this By

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6	settlement in a lawsuit filed against us by the l consumer protection agency.	Federal Trade Commission, the nation's	
7	1 8 1	Complete and Submit to Form	
8	[insert o	date 90 days after the date notice was provi pursuant to Provision VI.A.1. of the Ord	
9		pursuant to Frovision VI.A.T. of the Ore	
10	First Name		
11	Last Name		
11	Address		
12	City		
13	State ZIP Code		
13	Email Address		
14	Product Serial Number (Optional)		
15			
16	Original		
17		(Breeze)	
10			
18	☐ I bought a Breathometer Original for \$49.99.	☐ I bought a Breathometer Breeze for	
19	Please send me a refund.	\$99.99. Please send me a refund.	
20			
20	☐ I bought a Breathometer Original for	☐ I bought a Breathometer Breeze for	
21	\$ (fill in amount you paid). Please send me a refund.	\$ (fill in amount you paid). Please send me a refund.	
22	Trease send me a refund.	Trease send me a refund.	
23			
	Signature		
24	(type your name, this is your electronic signature)		
25	Date	,	
26	SUBMIT [clickable button]		
27			
28	Contact us at [800-xxx-xxxx] or BAC@bre	athometer.com if you have any questions.	
/ X	II		