PIVOT BREATH SENSOR STUDY

[redacted]

PROTOCOL NUMBER: [redacted]

DATE: September 12, 2019

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Synopsis

Device Names	Pivot Breath Sensor
Protocol Title	Pivot Breath Sensor Study [redacted]
Principal Investigator	[redacted]
Co-Investigators	[redacted]
Protocol Number	[redacted]
Protocol Version	[redacted]
Sponsor	Carrot Inc., [redacted]
Study Design	Prospective open label, single center study enrolling up to 220 participants to evaluate the effect of the Pivot Breath Sensor on a user's attitudes towards quitting smoking and smoking behavior.
Primary Objective	The primary objective is to collect the following data during and after use of a personal carbon monoxide breath sensor (Pivot Breath Sensor): • Change in attitudes towards quitting smoking • Change in smoking behavior (quit attempts, cigarettes smoked per day) • Participant feedback
Potential Subjects	Up to 220 subjects, comprising 2 cohorts: • 40-60% of participants who self-report smoking 10-19 cigarettes per day AND • 40-60% of participants who self-report smoking 20 or more cigarettes per day
Inclusion Criteria	• 18-80 years of age • Current daily cigarette smokers (at least 10 cigarettes per day) • Resident of the United States • Able to read and comprehend English • Owns and uses a smartphone compatible with the study app (iPhone 5 and above with operating system iOS 11 and above, or, Android 5.0 and above with operating system Android 5.0 and above) • Willing to sign the Informed Consent Form
Exclusion Criteria	• Pregnancy • Participation in a previous study sponsored by Carrot Inc.
Recruitment	Eligible subjects will be identified via web media (e.g., Facebook, Google ads) or via a clinical research recruiter.
Study Session	This is a prospective open-label sensor-only study conducted with IRB approval enrolling up to 220 subjects who report daily smoking of 10 cigarettes or more. The study will be performed remotely on an ambulatory basis. The subject will be asked to setup the Pivot Breath Sensor and provide

	breath samples for the 84-day duration of the study. Subjects will receive questionnaires at intervals throughout the study.
Data Collection	Data will be collected through an application (app) that the study participants install on their smartphone (the Sensor-Only app) and through participant completion of emailed online questionnaires.
Performance Variable	Assessment of the role of the Pivot Breath Sensor in attitudes towards quitting smoking and in smoking behavior: • Attitudes towards quitting: Stage of Change, desire to quit, confidence to quit, and difficulty to quit. • Smoking behavior: quit attempts, change in cigarettes per day (CPD), smoking cessation via 7-and 30-day point prevalence abstinence. • Participant feedback on the set-up, use experience, impact and commercialization of Pivot Breath Sensor.
Performance Endpoint and Analysis	Change from baseline measurement

Contents

1. LIST OF ABBREVIATIONS

CO	Carbon Monoxide
CPD	Cigarettes Per Day
CRF	Case Report Form
USB	Universal Serial Bus
IRB	Institutional Review Board
ICF	Informed Consent Form
HCP	Health Care Provider
ppm	parts per million

2. INTRODUCTION

2.1 BACKGROUND

The smoking of tobacco products is a leading cause of preventable morbidity and mortality, excess health care expenditure, and lost work productivity. [redacted]

[redacted]

Since our 2018 study, Carrot Inc. (Redwood City, CA, USA) has made improvements to the CO breath sensor (the Pivot Breath Sensor). The Pivot Breath Sensor consists of a stand-alone handheld breath sensor to measure CO in exhaled breath with a display screen to show results. This breath sensor can optionally be used with a smartphone app (Pivot Application). The Pivot Breath Sensor is intended to be used as a personal and mobile product and to be available 'over the counter'. In April 2019, a revised Pivot Breath Sensor was evaluated as comparable to its predicate device and considered cleared for marketing under 510(k) 171408.

There is anecdotal evidence that people can effectively use the Pivot Breath Sensor alone and gain meaningful positive changes in their attitudes and behavior such as motivation to quit and reduction in cigarettes, respectively. A goal the present study is to measure these changes in attitudes and behavior in participants using the Pivot Breath Sensor alone, without a complementary programmatic smartphone app.

2.2 STUDY RATIONALE

The study duration is 84 days with a focus on assessment of participant use of the Pivot Breath Sensor over this time period with associated participant feedback and measure of changes in attitudes towards quitting and smoking behavior.

2.3 POTENTIAL RISKS AND BENEFITS

2.3.1 Known Potential Risks

There are minimal anticipated risks or harms to the participant. Risks include breach of confidentiality should a data breach occur, and participant anxiety related to using the Pivot Breath Sensor multiple times a day. We, the study sponsor (Carrot Inc.) comply with HIPAA and state this in our privacy and terms of use on our website. As such, we adhere to HIPAA's Breach Notification Rule should a data breach occur. We take careful measures to prevent a data breach including use of encryptions, secure connections, and limited access to data (see section 10.1 "Data Collection and Confidentiality"). Regarding the risk of participant anxiety related to using the device multiple times a day, while there are suggested breath sampling patterns provided during the screening call and with the breath sensor, participants will ultimately sample at their discretion. No medical decisions are made based on study data.

2.3.2 Known Potential Benefits

While we do not anticipate that participants will receive any benefit from their participation in this study, it is possible that some participants may experience an increased awareness of their smoking behavior. It is possible this awareness and new information on how much carbon monoxide is in their body may help a participant quit smoking.

2.3.3 Risk Benefit Assessment

Given the non-invasive nature of the breath sampling and the data collection, there are minimal anticipated risks. These risks relate to breach of confidentiality in the circumstance of a data breach, and possible participant anxiety related to using the Pivot Breath Sensor multiple times a day. These risks have been mitigated to the extent possible through data protection measures and through enabling participants to ultimately decide if and when they do breath samples. Participants will have the remote support of study staff and customer support as they need over the course of the study. Participants are not asked to change their smoking behavior. No medical decisions are made based on study data.

3. OBJECTIVES

We aim to measure participants' use of the Pivot Breath Sensor (Pivot Breath Sensor, Carrot Inc.; Redwood City, CA, USA; 510(k) number: K171408) and to non-invasively measure their carbon monoxide (CO) levels in their exhaled breath. There will be a focus to assess changes in attitudes towards quitting smoking and changes in smoking behavior over the course of the 84-day study, as well as participant feedback on the set-up, use experience, impact and commercialization of the Pivot Breath Sensor.

References

- FDA Guidance Document Entitled, "Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices," issued on February 3, 2016
- FDA Guidance Document Entitled, "Design Considerations for Devices Intended for

Home Use, Guidance for Industry and Food and Drug Administration Staff" issued on November 24, 2014
- ISO/IEC 62366-1:2015, Medical devices – Application of usability engineering to medical devices. Geneva, International Electro technical Commission.
- AAMI/ANSI HE75:2009, Human Factors Engineering – Design of Medical Devices.
- https://www.bluetooth.com/what-is-bluetooth-technology/bluetooth-technology-basics

4. DEFINITIONS

Bluetooth Low Energy (BLE): a global wireless communication standard that connects devices together over a certain distance.

Data: Data collected through the Pivot Breath Sensor, Sensor-Only app and participant-completed online email questionnaires

Pivot Breath Sensor: The study device; a personal mobile breath sensor that is capable of measuring the level of carbon monoxide (CO) in exhaled breath. It is portable, battery-powered, and small enough to be carried by the user throughout the day (pocket, purse, backpack). The sensor is intended for single-user use by cigarette smokers to inform the user about how breath carbon monoxide levels are affected by smoking behavior. The user submits a breath sample by exhaling (blowing) directly into the mouthpiece connected to the sensor with breath sample results displayed on a screen on the sensor.

User: Person who interacts with (i.e., operates or handles) the Pivot Breath Sensor.

Sensor-Only app: App installed on user's smartphone. User's smartphone is connected to the Pivot Breath Sensor via BLE. Participant breath sensor usage data and carbon monoxide results populate the Sensor-Only app and are available to the study team in real-time.

5. DEVICE DESCRIPTION

5.1 PIVOT BREATH SENSOR, STUDY DEVICE

The Pivot Breath Sensor comprises a personal mobile breath sensor that measures the level of CO in exhaled breath and displays the exhaled breath CO value to the user directly on the device. The range of CO measurement is 0-100 ppm.

The Pivot Breath Sensor (Figure 1) is portable, battery-powered, and small enough to be conveniently carried by the user throughout the day (pocket, purse, backpack). The Pivot Breath Sensor is rechargeable using a micro-USB cable. The user submits a breath sample by exhaling (blowing) into the mouthpiece of the Pivot Breath Sensor.

5.1.1 Indications for Use

The Pivot Breath Sensor is a breath carbon monoxide monitor intended for single-user use by cigarette smokers to inform the user about how breath carbon monoxide levels are affected by smoking behavior. The device is not intended to be used with other inhaled products.

Figure 1. Pivot Breath Sensor

5.2 LABELING AND PACKAGING

The Pivot Breath Sensor package includes:

- 1 Pivot Breath Sensor
- 1 USB charging cable
- 1 Replaceable Mouthpiece
- 1 Quick Start Guide [redacted]
- 1 Packaging Insert [redacted]

The Pivot Breath Sensor packaging is shown in [redacted]

5.3 PIVOT BREATH SENSOR SUBMITTING A BREATH SAMPLE (SPECIFIC STEPS)

Submitting a breath sample involves the following steps. Instructions can be accessed in multiple locations including the Pivot Sensor's display screen, in the online User Manual [redacted] Quick Start Guide, and on the packaging.

1. User presses any button to turn on the Pivot Breath Sensor.
2. User presses and holds the center button on the Pivot Breath Sensor until the sensor beeps once.
3. User takes a deep breath in and holds their breath for 10 seconds.
4. After about 10 seconds, the device beeps 3 times, and the user then will exhale slowly until the sensor vibrates at 12 seconds.
5. The user's CO level will display on the sensor's screen.

A properly submitted breath sample is defined as one that initiates after the third beep prompt and is of at least 6 seconds duration. Breath sensor hardware and firmware is capable of detecting when a breath sample submission starts and stops.

The CO Log screen on the Pivot Breath Sensor provides the CO (ppm) value for properly submitted breath samples.

The computation of concentration of CO (ppm) is performed within the Pivot Breath Sensor firmware and the data (CO ppm concentration, time and date) are stored in the Pivot Breath Sensor memory. This data is also stored in the Sensor-Only app when the

Pivot Breath Sensor and user's smartphone app are paired. Opening the app syncs the data to its most updated state, which study staff may access in real-time. User's may also sync their breath sensor data by tapping the breath sensor icon in the upper right corner of the app and then tapping "Sync Now' in the dropdown menu.

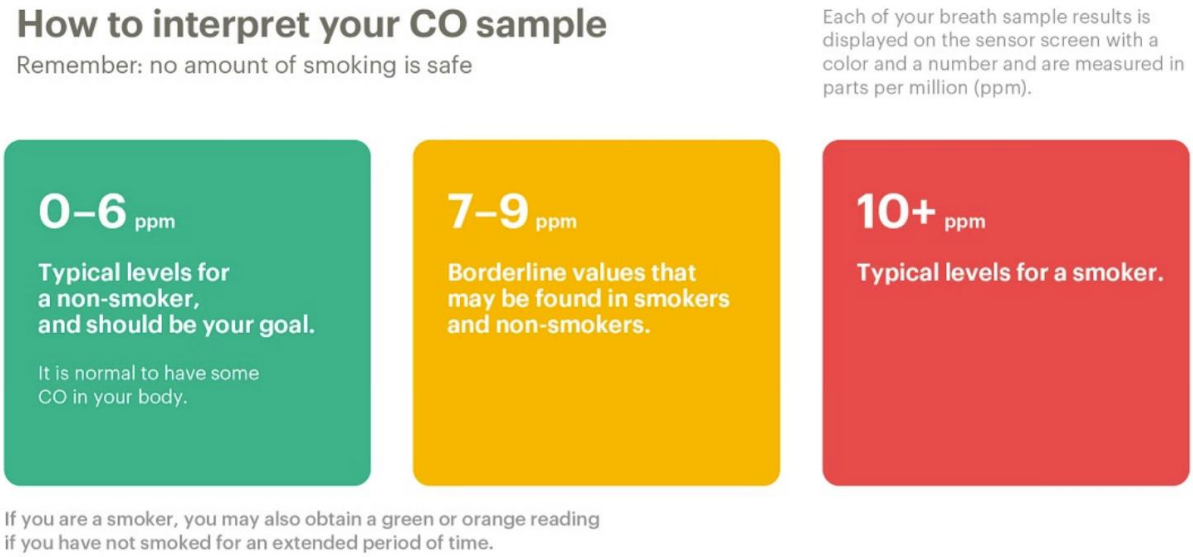
5.4 CO LOG

The CO Log can be accessed from the Pivot Breath Sensor's display screen and shows the most recent exhaled breath CO value in ppm at the top of the screen. The user can view previous values by scrolling within the log (Figure 3).

Values are color coded and can be interpreted by the user with help from the labeling (Figure 4).

Figure 3. CO log on Pivot Breath Sensor

Figure 4. Package labeling to interpret results



CO values are also stored in the Sensor-Only app on the participant's smartphone. When the Pivot Breath Sensor is paired to a user's phone, his/her CO values, date/time of breath samples, and any error codes populate the Sensor-Only app; this data is accessible to study staff in real-time but is not visible to study participants.

6. STUDY DESIGN AND OVERVIEW

6.1 STUDY DESIGN

This is a prospective open-label sensor-only study conducted with IRB approval enrolling up to 220 subjects who report daily smoking of 10 cigarettes or more. The study will be performed remotely on an ambulatory basis. The participant will be asked to setup the Pivot Breath Sensor and participate for 84 days with an emphasis on providing breath samples and completing online study questionnaires. The suggested breath sampling regimen is at least 4 breath samples per day, spread over the course of the day. Participants will receive the online questionnaires via email at intervals throughout the study.

6.2 STUDY DURATION

The study will run for 84 days (+ up to 14 days to obtain completion of the final questionnaire), with questionnaires emailed at baseline, 7, 14, 21, 28, 56 and 84 days.

6.3 STUDY OUTCOMES

- Attitudes towards quitting: Stage of Change, desire to quit, confidence to quit, difficulty to quit, goals
- Smoking behavior: quit attempts, change in cigarettes per day (CPD), smoking cessation via 7- and 30-day point prevalence abstinence.
- Participant feedback on the set-up, use experience, impact and commercialization of the

Pivot Breath Sensor.

The primary endpoint will assess any change in the proportion of participants' Stage of Change response at day 28 compared to baseline

- A positive outcome is defined as a participant responding as more ready to quit. For example, a change in response from seriously thinking of quitting smoking "…within the next 6 months" at baseline to seriously thinking of quitting smoking "…within the next 30 days" at day 28.

The secondary endpoints include:

- The proportion of participants who reported ≥ 1 quit attempt by day 28; will be compared to zero
    - A quit attempt is defined as answering ≥ 1 to the following question: "Since you began using the Pivot Breath Sensor, how many times have you tried to quit smoking where you've gone at least 1 day without smoking a cigarette, even a single puff?)"
- The proportion of participants who reduced their cigarettes per day (CPD) by ≥ 50% by day 28, compared to baseline

Eligibility Criteria

The anticipated initial user population for the Pivot Breath Sensor System are lay users who are smokers, ages 18-80, and capable of using a smartphone to download the Sensor-Only app. The intended users range in age, degree of smoking, mental and physical capabilities, health literacy, experience using other CO analyzers or home use medical devices, and experience using smartphones.

Study participants will consist of individuals who represent the intended user profile, current smokers. Participant criteria include all of the following:

Inclusion Criteria

- 18-80 years of age
- Current daily cigarette smokers (at least 10 cigarettes per day)
- Resident of the United States
- Able to read and comprehend English
- Owns and uses a smartphone compatible with the study app (iPhone 5 and above, operating system iOS 11 and above, or, Android 5.0 and above, operating system Android 5.0 and above)
- Willing to sign the Informed Consent Form

Exclusion Criteria

- Pregnancy
- Participation in a previous study sponsored by Carrot Inc.

The study will employ non-proportional quota sampling as follows to ensure the study population mirrors the expected initial intended user population:

Age	18-29 years ≤ 20 % of sample	30-60 years Remainder	61-80 years ≤ 10 % of sample
Stage of Change*	Quit 30 days ≥ 20% of sample	Quit 6 months ≥ 20% of sample	Not interested < 20 % of sample
Gender	Male 40-60%	Female 40-60%	
Cigarettes Per Day (CPD)	10-19 CPD 40-60%	≥ 20 CPD 40-60%	
Employment**	Unemployed 4-8% of sample	Employed Remainder	

- *Stage of Change question and answer choices: Are you seriously thinking of quitting smoking? A. Yes, within the next 30 days B. Yes, within the next 6 months C. No, not thinking of quitting
- ** Employment rate among study participants is sought to align with employment rates among the general US population, which currently is 3.7% (Bureau of Labor Statistics, U.S. Department of Labor. The Employment Situation – July 2019. USDL-19-1388. Released August 2, 2019. https://www.bls.gov/news.release/pdf/empsit.pdf)

6.4 SUBJECT RECRUITMENT, INFORMED CONSENT AND ENROLLMENT

Subjects will be recruited in the United States through web media (e.g. Facebook, Google Ads) [redacted] and/or via a clinical recruiter. Potential participants will be asked to provide contact information (phone number, email address), and answer questions on demographics (gender, age, employment status, location via city and state), smartphone ownership and smoking behavior using the Online Screening Form [redacted] or through the clinical research recruiter, if applicable. Study staff will review each potential participant's responses to the eligibility questions. Potential subjects may also convey their interest in participating in the study by responding to outreach from the clinical recruiter.

All study participants will undergo a screening phone call where they will be asked questions to confirm study eligibility [redacted]. Potential participants will be called on a first-come-first-served basis with nonproportional quota sampling enrollment guidelines applied. During this call, study personnel will inform the potential participant of the study details and will answer any questions. Eligible participants who meet the inclusion/exclusion criteria will be offered the opportunity to participate in the study.

Potential subjects will then determine if they would like to proceed with registration, and if so, study personnel will email the potential subject an electronic Informed Consent Form [redacted] The potential subject will have ample time to read the Informed Consent Form (ICF) and the opportunity to ask questions. The subject will sign the

electronic ICF before participating in this study. Once signing the ICF, the subject will be given a unique identifier to protect subject privacy. Participation in this research is voluntary. Participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled. Participants may choose to exit the study at any time. They are not required to complete the study if they choose to stop.

Participants will be considered enrolled after completing the following 4 tasks: electronically signing the informed consent form, pairing their breath sensor to the Sensor-Only app on their smartphone, giving their first breath sample, and completing the Baseline Questionnaire.

6.5 SUBJECT STIPEND

Participants are compensated for doing breath samples (up to $220), completing the online questionnaires (up to $220 in total for 7 questionnaires) and for returning the Pivot Breath Sensor ($50). Participants will be compensated up to $490 in total. Compensation will be in the form of Visa gift cards that are mailed to their provided address. Payments will be bundled as depicted in the Informed Consent Form with participants receiving up to 5 payments over the course of the study. Bundled payments will be processed upon completion of the item(s) for which the participant is receiving payment and will take 2-3 weeks to arrive to the participant after being ordered.

6.6 SAMPLE SIZE AND JUSTIFICATION

This study will enroll up to 220 participants. Consideration for the sample size included powering the study to observe a clinically meaningful change from baseline for the primary and secondary endpoints using 80% power at a statistical significance of $P < 0.05$. The primary endpoint utilized preliminary data from a similar 37 participant pilot study. Data at the 14-day time point showed 31%, 66% and 3% of participants had increased, unchanged and decreased Stage of Change, respectively, from baseline. To detect a statistically significant change in these proportions requires enrolling 50 participants.

The estimated proportion of participants achieving ≥ 1 quit attempt is 25% based on interim results from the pilot study. Based on the median prevalence of 65.4% for past-year quit attempts in the general population [13], the average monthly quit attempt rate is approximately 5%. To show that a proportion of 25% of participants making a quit attempt by day 28 is statistically different from 5% will require n=16.

Finally, literature indicates approximately 1% of the general population [14-18] and 2-5% of individuals in cigarette reduction studies [19, 20] will reduce their CPD by ≥ 50% on a monthly basis. Assuming that 10% of participants in the present study reduce their CPD by ≥ 50% by day 28, the present study will require n=185 to show a difference from 5%. Taking these analyses into consideration along with expected attrition, the present study will enroll up to 220 participants.

6.7 STUDY ARTICLES

Pivot Breath Sensor in representative packaging [redacted] that includes:

- Pivot Breath Sensor
- USB charging Cable
- Replaceable Mouthpiece
- Quick Start Guide [redacted]
- Sensor-Only App [redacted]
- Package Insert [redacted]

6.8 USER MANUAL AND TRAINING

The Pivot Breath Sensor was designed to be as intuitive as possible, such that users are able to understand how to use the product on their own. A Quick Start Guide, Package Insert, and package labeling is included with the device to aid the user and an online User Manual is also available. All of these items will be accessible to the study participant. A phone number will be included within the labeling material to contact customer support. In this study, users will be contacted via phone, email and/or text to check on the status of the device setup. Help will be offered if the user is having difficulty.

6.9 TEST ENVIRONMENT

The study will be performed remotely on an ambulatory basis. The device will be mailed to the participant's indicated address and the participant will use it throughout their day, going about life as they normally would.

6.10 STUDY PERSONNEL

The study team members will be trained by reading the study protocol. The study team members will have full training on the operation of the study devices and Sensor-Only app.

6.11 IRB OVERSIGHT

This study will be conducted under IRB oversight.

7. STUDY PROCEDURE

7.1 SCREENING

See section 6.5 Subject Recruitment, Informed Consent and Enrollment

7.2 REGISTRATION

After electronically signing the Informed Consent Form, the subject will be directed to the online registration page [redacted]. After registration is complete, the Pivot Study team will mail the sensor and email the subject the Baseline Questionnaire (age, gender, ethnicity, education, income, smoking history and behavior, use of smoking cessation medications, and attitudes and goals towards smoking) [redacted]

7.3 DAY 1 – DATE PAIRED DEVICE, GAVE FIRST BREATH SAMPLE AND COMPLETED BASELINE QUESTIONNAIRE

Upon receipt of the sensor, the participant will self-train on how to use the study device using the available study Pivot Breath Sensor device labeling, including product packaging, Quick Start Guide, Package Insert, and a technical support line (phone number provided in packaging/Quick Start Guide) and online User Manual if needed. A member of the study staff or customer support may optionally call, text or email the participant to assist in device setup.

The participant will initiate using the product. Enrollment date (Day 1) will be defined as the first day the participant has completed all of the following: paired their breath sensor to the Sensor-Only app, taken their first breath sample using the Pivot Breath Sensor, and completed the Baseline Questionnaire.

7.4 DAYS 1 THROUGH 84 – BREATH SAMPLING

Study participants will be instructed to use the breath sensor daily for the duration of the study, with a recommendation that they do at least 4 breath samples a day, spread over the course of the day. This suggested use pattern is provided in the labeling materials and during the screening phone call but breath sensor use is ultimately at the discretion of the participant. Participants may receive twice weekly text instructions to sync their breath sensor data to the app. This will enable the study team to track participant breath sensor data as the study proceeds.

7.5 DAYS 1 THROUGH 84 – STUDY QUESTIONNAIRES

Participants will receive periodic electronic questionnaires via email (Survey Monkey) that focus on attitudes towards quitting, smoking behavior, and participant feedback on breath sensor set-up, user experience, impact and commercialization (Section 7.7). Participants will receive periodic reminders from study staff to complete the questionnaires via email, text or phone, as needed. All participants will receive the 28-day and 84-day questionnaires, regardless of previous completion of questionnaires.

7.6 DAY 84 AND STUDY COMPLETION

Upon completion of the study, the participant will receive the electronic final questionnaire; the participant will have up to 14 days to complete the final questionnaire once it has been emailed to them. The participant will be asked to send the Pivot Breath Sensor back using a provided pre-paid mailer.

7.7 SCHEDULE OF STUDY ACTIVITIES

Event	Screening[1]	Registration	1	7	14	21	28	56	84	84-98
Eligibility confirmed	X									
Phone call	X		X[3]							
Informed consent		X								
Receive breath sensor[2]			X							
Active use of breath sensor			X	X	X	X	X	X	X	
Survey		X		X	X	X	X	X	X	
- Baseline and demographic data		X								
- Access device settings				X	X	X	X	X	X	
- Feedback: breath sensor set-up				X						
- CPD		X		X	X	X	X	X	X	
- Desire to quit		X		X	X		X	X	X	
- Difficulty to stay quit		X		X	X		X	X	X	
- Stage of Change		X		X	X		X	X	X	
- Readiness to quit		X		X	X		X	X	X	
- Confidence to quit		X		X	X		X	X	X	
- Goals		X		X	X		X	X	X	
- Point prevalence abstinence					X	X	X	X	X	
- Quit attempts		X			X		X	X	X	
- CO reading understanding				X	X		X	X	X	
- Feedback: breath sensor experience and use				X	X		X	X	X	
- Feedback: impact of breath sensor				X	X	X	X			
- Feedback: commercialization					X		X			
Final questionnaire										X
Return breath sensor										X
Study completion										X

1 Screening is a phone call to prescreened candidates based on their responses to an online screening questionnaire.
2 Pivot Breath Sensor received by participant only after confirmation of eligibility and provision of electronic informed consent.
3 Optional phone call to assist with breath sensor set-up as needed

8. DATA COLLECTION

Study personnel will collect information from the participant over the course of the study including:

- Age
- Gender
- Pregnancy status (self-reported) in women
- Race/ethnicity
- Type of smartphone participant used (iPhone or Android)
- Number of years smoking
- Quit attempts
    - Past 12 months
    - During the study
- Number of cigarettes currently smoked per day (CPD)
- 7-day point prevalence abstinence (PPA)
- 30-day point prevalence abstinence (PPA)
- Use of any combustible, inhaled tobacco product other than cigarettes (pipes, cigars, cigarillos, etc.), any electronic cigarette product (e-cigs, vape, vapor), and any other inhaled combustible material
- Use of smoking cessation medications
- Participation in a smoking cessation program
    - Past
    - Present
- Ability to access settings (sensor battery life reading and "Sync Now" function) in the Sensor-Only app
- Attitudes towards smoking
    - Desire to quit (y/n)
    - Stage of Change
    - Readiness to quit (scale 1-10)
    - Confidence to quit (scale 1-10)
    - Perceived difficulty of staying quit (scale 1-10)
    - Goals
- Feedback on breath sensor set-up
    - Ease/difficulty getting started with the breath sensor (scale 1-5)
    - Ease/difficulty following directions on the breath sensor screen (scale 1-5)
    - Ease/difficulty of to understand error messages on breath sensor screen if applicable (scale 1-5)
- Feedback on breath sensor experience and use
    - How would you improve the Pivot Breath Sensor experience?
    - Please describe any issues you've had with the breath sensor
    - How likely are you to recommend the Pivot Breath Sensor to a friend/colleague? (scale 1-10)
    - Do you use the breath sensor at least once a day (if not, why?)
    - Are you using the breath sensor as often as you did in the beginning of the program? (if not, why?)

    - Which of the following best describes your thoughts on the Pivot Breath Sensor? ('nothing else can help me with smoking' to 'it will not help me with smoking')
- Feedback on impact of breath sensor
    - Comprehension of CO and CO values as they relate to smoking behavior
    - How has seeing your CO values impacted you as it relates to:
        - your feelings?
        - learning?
        - your thoughts about smoking and daily smoking behavior?
        - your thoughts about quitting?
    - How has the breath sensor affected your motivation to quit smoking? (increase, no change, decrease)
    - How has the breath sensor affected the number of cigarettes you smoke per day? (increase, no change, decrease)
    - Which of the following best describes the Pivot Breath Sensor's ability to help someone quit smoking? ('extremely helpful' to 'makes quitting smoking harder')
    - Which of the following best describes what you have learned from using the Pivot Breath Sensor ('really unique/key insights' to 'I am more confused after using the sensor')
    - Has the breath sensor taught you about your CO levels? (y/n)
    - Has the breath sensor taught you about your smoking behavior? (y/n)
    - What are your initial impressions of the booklet titled "The Pivot CO Sensor: Prepare to be blown away", found inside the sensor box?
    - Do you have a better understanding about CO levels and your smoking behavior because of the breath sensor? (y/n)
    - How well do you understand CO in general? (1 = not at all, 10 = completely understand)
    - How well do you understand your CO levels and trends as they relate to your smoking behavior? (1 = not at all, 10 = completely understand)
- Feedback on commercialization
    - Hypothetical: if it was commercially available, would you be interested in buying the Pivot Breath Sensor? Why or why not?
    - What is a reasonable price for the Pivot Breath Sensor? Why?
    - How would you describe your need for the Pivot Breath Sensor? ('I really need this product' to 'I am not interested at all in this product')

9. TECHNICAL APPROACH AND STUDY DESIGN

9.1 ACCEPTANCE CRITERIA

Data will be accepted if the participant meets eligibility criteria, and completes the electronic informed consent form, web registration, at least one breath sample (as indicated the Sensor-Only app) and the Baseline Questionnaire.

10. STUDY RESULTS

10.1 DATA COLLECTION AND CONFIDENTIALITY

Participants will be assigned a unique participant ID which will be used for data collection. Data collection will take place on electronic case report forms (CRFs)

completed by study participants and through data collected in the Sensor-Only app (participant breath sensor usage and CO values of breath samples). CRFs will be reviewed by the study team prior to the end of the study to ensure completeness. Access to electronic CRFs will be limited to necessary study personnel. Study data will be kept in a secure database by the investigator. This database will be accessible only by necessary study personnel. The database will not contain personal identifying information; all subject data in the database will be associated with study identification numbers. The data will be kept for a minimum of 5 years. The data shall be retained for a maximum period of time that is equivalent to the design and expected life of the Pivot Breath Sensor device or the duration of the study sponsor's (Carrot Inc.) existence, whichever is the shortest of the two.

Data on the breath sensor will be accessed with an app customized for this study. This Sensor-only app is our commercially available app with select function disabled. The app to be used in this study will request location permissions in order to complete the Bluetooth scanning and pairing process with the sensor. Other features to access functionality (e.g camera, microphone) are disabled for this study. With regard to the information we will collect, we, the study sponsor, associate each logged in user to a user Id that is a unique identifier which is generated randomly on account creation. We will periodically synchronize logs from the sensor and upload them based on this user_Id only. The breath samples we collect only contain information regarding: Sample Id, Sample Type, SampleValue, Sample Time. When we upload this information, the only additional information included would be the App build information and user's Sensor ID. We comply with HIPAA and state this in our privacy and terms of use on our website. As such we adhere to HIPAA's Breach Notification Rule should a data breach occur. We take careful measures to prevent a data breach including use of encryptions, secure connections, and limited access to data.

10.2 ANALYSIS

Changes in measurements from baseline will be assessed at different timepoints in the study. Participants will serve as their own controls and comparisons will be made to no change. One sample t-test will be used for numerical data. Fisher's Exact or Chi square tests will be used for categorical data. Analyses will be conducted to calculate mean (SD) for normally distributed variables for actual data or mean (SE) for modeled data and median (interquartile range) values in instances of non-normally distributed variables.

McNemar test will be used for 2-category match-paired data. Cohen kappa statistic will be used for 3-category match-paired data. To evaluate changes in attitudes or cigarettes smoked per day over time, repeated measures linear mixed model analyses will be performed using a compound symmetric correlation matrix to model the repeated measures within subjects. To make specific comparisons across time, F statistics will be computed using the results from the model. Statistical significance is set at $P<.05$.

Analyses for the outcomes will be evaluated for only those who complete the survey (i.e. completer) and assessed to take into account missing data. To be included in any completer analysis the participant must provide a baseline response and the outcome response. For outcomes that are missing data, these will be assessed pending the data type.

For categorical data, the last response post-baseline will be carried forward for the day 28 analysis and the last response post-28 days will be carried forward for the day 84 assessment. If there is not any data to carry forward, the data will be considered unchanged from baseline. Numerical data will use linear mixed modeling.

All deviations from the study protocol will be identified, recorded and analyzed.

10.3 STUDY REPORT

A final study report will be produced at the end of the study; PowerPoint format is acceptable. The report will detail participant characteristics, breath sensor usage, the aforementioned outcomes of changes in attitudes towards quitting and smoking behavior as well as participant feedback.

10.4 DEVIATIONS FROM PROTOCOL

To be determined by the study team during the study. Deviations will be assessed through a consensus review of the study team. All deviations will be identified, recorded and analyzed in the final report.

10.5 RECORD RETENTION

Record keeping is performed in accordance with the SOP Control of Quality Records, [redacted]

11. CONFLICTS OF INTEREST

The following conflicts of interest are noted:

- The study sponsor is Carrot Inc., [redacted]
- The principal investigator and co-investigators own equity in Carrot Inc., which is the company that invented and owns the Pivot Breath Sensor, which is being evaluated in this study.
- The company (Carrot Inc.) holds patent rights to one of the devices being evaluated in the study (the Pivot Breath Sensor).

The investigator [redacted] holds a position of senior management officer, as Sr. Director of Clinical and Medical Affairs. The Co-Investigator [redacted] holds a position of Director of Clinical Affairs. The Co-Investigator [redacted] holds a position of Senior Clinical Research Associate. These conflicts of interest are mitigated by the following:

- The risk profile of the study, specifically, that there are minimal anticipated risks or harms to the subject. No medical decisions are made based on study data. The process of setting up the Pivot Breath Sensor and providing breath samples is non-invasive, and participants have access to trained study and customer support personnel for assistance as needed. Breath samples are done at the discretion of the study participant.
- The role of Carrot Inc. in the study is outlined in the study Informed Consent Form; participants will be aware of this role prior to providing informed consent.
- The aim of the study is to assess the performance of the Pivot Breath Sensor in intended

users and then use this data to inform future studies and optimize the product as needed. This study will inform resultant improvements made to the Carrot Inc. products (the Pivot Breath Sensor). As such, it is imperative, and the goal, that the study sponsor uses this data to ensure its products are as user-friendly and accurate as possible.

12. [redacted]

[redacted]

13. **LITERATURE REFERENCES**

[redacted]

14. **DOCUMENT REVISION HISTORY:**

Rev. A Original Protocol
Rev. B Added the following text to section 10.1 “Data Collection and Confidentiality” regarding the maximum time data will be retained: “The data shall be retained for a maximum period of time that is equivalent to the design and expected life of the Pivot Breath Sensor device or the duration of the study sponsor's (Carrot Inc.) existence, whichever is the shortest of the two.” Section 2.3 “Potential Risks and Benefits” was updated to include possible risks of data breach and participant anxiety associated with using the Pivot Breath Sensor multiple times a day.