PIVOT BREATH SENSOR HUMAN FACTORS AND USABILITY STUDY PROTOCOL [redacted]

PROTOCOL NUMBER: [redacted]

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Synopsis

Device Names	Pivot Breath Sensor
Protocol Title	Pivot Breath Sensor Human Factors and Usability Study [redacted]
Principal Investigators	[redacted]
Co-Investigators	[redacted]
Protocol Number	[redacted]
Protocol Version	[redacted]
Sponsor	Carrot Inc., [redacted]
Study Design	Prospective, observational open label, single center study enrolling up to 15 subjects to evaluate human factors and usability of the Pivot Breath Sensor. No medical decisions will be made related to test results.
Primary Objective	Human Factors and Usability: • Ensure that intended users are able to operate the Pivot Breath Sensor independently • Validate appropriate mitigations of use related hazards identified in risk management documentation. • Uncover previously unforeseen use errors.
Potential Subjects	• Up to 15 subjects who self-report smoking 2 or more cigarettes each day.
Inclusion Criteria	• 18-80 years of age • English speaking • Owns and uses a smartphone • Willing to sign the Informed Consent Form
Exclusion Criteria	• Prior experience with a study sponsored by Carrot Inc • Pregnancy
Recruitment	Eligible subjects will be identified via a clinical research recruiter and/or advertisement at outdoor locations (i.e. flea markets, outside of movie theaters, shopping malls, train stations, stores that sell cigarettes), print media (i.e., local newspapers, billboards), and web media (i.e., Craigslist, Facebook).
Study Session	Single day study including: observation of user set up and use of the Pivot Breath Sensor, user documentation assessment, subjective feedback and rating scales.
Human Factors and Usability Outcomes	Assessment of intended user performance in use scenarios, user documentation assessment, subjective feedback and rating scales.

Contents

1. LIST OF ABBREVIATIONS

CO	Carbon Monoxide
CRF	Case Report Form
USB	Universal Serial Bus
IRB	Institutional Review Board
ICF	Informed Consent Form
ppm	parts per million
QSG	Quick Start Guide
UM	User Manual

2. INTRODUCTION

2.1 BACKGROUND

Smoking 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'.

This study will assess the human factors and the usability of the Pivot Breath Sensor.

2.2 STUDY RATIONALE

We aim to assess whether an untrained lay user group (representative of intended users) can operate the device and interpret the results correctly using only the instructions that will be provided with the marketed device.

2.3 POTENTIAL RISKS AND BENEFITS

2.3.1 Known Potential Risks

There are no anticipated risks or harms to the subject. No medical decisions are made based on study data.

2.3.2 Known Potential Benefits

While we do not anticipate that subjects will receive any benefit from their participation in this study, it is possible that some subjects may experience an increased awareness of their smoking behavior.

2.3.3 Risk Benefit Assessment

Given the non-invasive nature of the breath sampling and the data collection, there are no anticipated risks to subject safety. Study staff will be with subjects and monitoring their use of the study devices for the duration of the study. Subjects are not asked to change their smoking behavior. No medical decisions are made based on study data.

3. OBJECTIVES

The objectives of the study are to:

- Ensure that representative intended users are able to operate the Pivot Breath Sensor independently, focusing on the following:
  - Proper breath sample collection
  - User comprehension of how to navigate the Pivot Breath Sensor screen
  - User interpretation and comprehension of their results
- Validate appropriate mitigations of use related hazards identified in risk management documentation
- Uncover previously unforeseen use errors

Overall, this human factors and usability testing is conducted to demonstrate that the Pivot Breath Sensor can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions.

4. 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

5. DEFINITIONS

Close Call (a.k.a. "Near-Miss"): Instances in which a user has difficulty or makes a use error that could result in harm, but the user takes an action to "recover" and prevents the harm from occurring (FDA Guidance 2016).

Critical Task: A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient, user, or instrument, where harm is defined to include compromised medical care.

Objective Data: Data collected through direct observation.

Pivot Breath Sensor: The study device. It is 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.

Subjective Data: Data collected through user feedback via comments, ratings, and assessments provided by participants.

Task: Action or set of actions performed by a user to achieve a specific goal.

Use Error: User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by device failure and (3) did or could result in harm. (Section 3.9, FDA Guidance 2016).

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

6. 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.

6.1 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

6.2 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]

The Pivot Breath Sensor packaging is shown in [redacted]

6.3 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, the Quick Start Guide, on the packaging or also in the User Manual that will be available online.

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, 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 in the Pivot Breath Sensor provides the CO (ppm) value for properly submitted breath samples and provides a descriptive error message for improperly submitted breath samples (i.e. "Error: breath sample too late").

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.

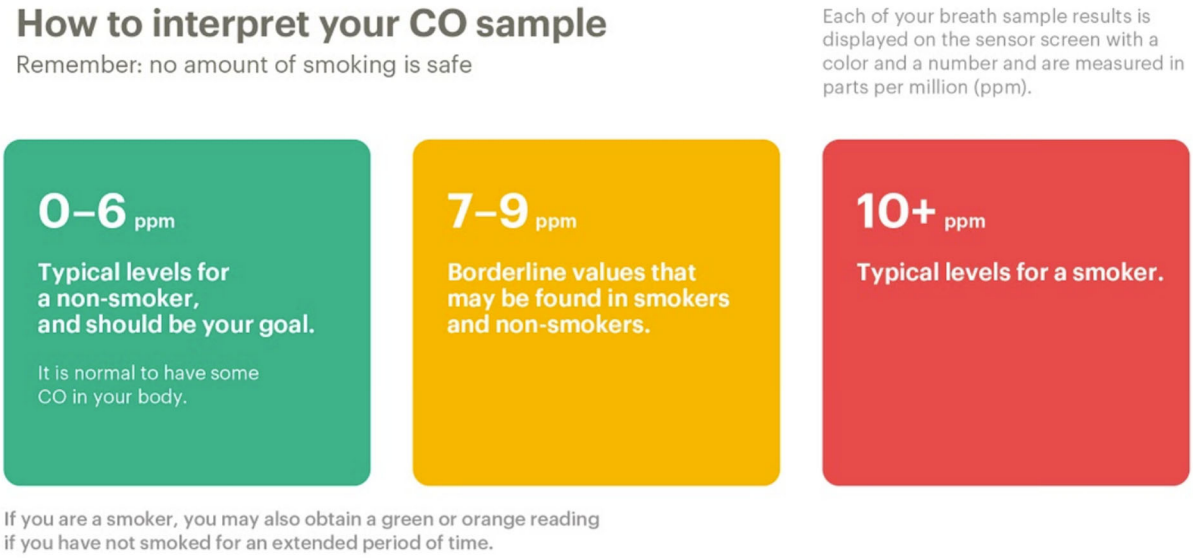
6.4 CO LOG

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 2).

Values are color coded and can be interpreted by the user with help from the labeling (Figure 3).

Figure 2. CO log on Pivot Breath Sensor

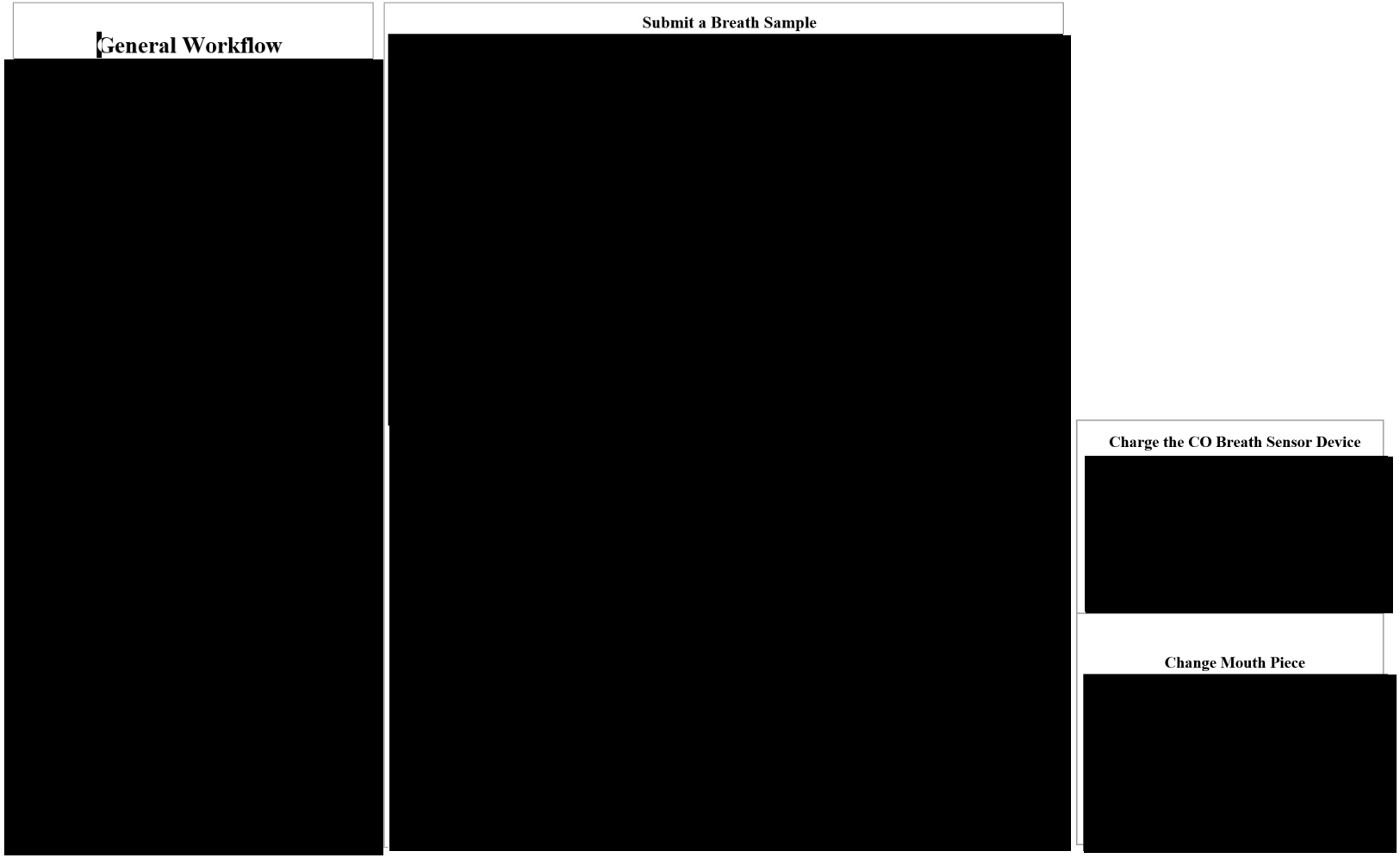
Figure 3. Package labeling to interpret results



7. TASK ANALYSIS AND IDENTIFICATION OF CRITICAL TASKS

For the human factors and usability portion of the study, a task analysis was performed to identify the tasks associated with the use of the Pivot Breath Sensor. The task analysis is depicted in Figure 4.

Figure 4. Task Analysis of Pivot Breath Sensor
(Note: Sub-work flow is shown in lighter blue.)



As part of the product development process, a comprehensive use related failure mode and effect analysis (Use FMEA) was performed to identify and analyze the potential use-related failure modes (i.e., use errors) that might occur when the intended users interact with the Pivot Breath Sensor.

The task analysis and the Pivot Breath Sensor Use FMEA were assessed for critical tasks. Based on the definition of a critical task provided in FDA "Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices," issued on February 3, 2016 ("A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care"), it was identified that the Pivot Breath Sensor does not have use related tasks that may result in serious harm or compromised medical care if the device is not operated properly by the user. [redacted] Carrot Inc. chose to perform usability testing to assess user tasks and comprehension items that are essential to the effective operation of the device and user interpretation of breath sample results, and, to monitor for unforeseen use errors that could lead to serious harm.

Table 1. List of "Severity 2" Tasks

User Tasks and Comprehension Items	Severity
[redacted]	

8. STUDY DESIGN AND OVERVIEW

8.1 STUDY DESIGN

This is a prospective open-label human factors and usability study, conducted with IRB approval, enrolling up to 15 subjects who report daily smoking. The study will be conducted at our research center in Redwood City, CA or an equivalent location. Subjects will be asked to set up the Pivot Breath Sensor and provide a breath sample using the device during a 60-minute session. No follow-up visit is required.

8.2 STUDY ENDPOINTS

Assessment of intended user performance in use scenarios, user documentation assessment, subjective feedback, and rating scales.

8.3 ELIGIBILITY CRITERIA

The intended user population (user group) for the Pivot Breath Sensor System are lay users who are smokers, ages 18-80, capable of using a smartphone to track/monitor health-related data. 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 2 cigarettes per day with target distribution of individuals who smoke: 2-5 cigarettes per day, 6-10 cigarettes per day, 11-15 cigarettes per day and 16+ cigarettes per day)
- Resident of the United States
- Able to read and comprehend English
- Currently own and use an Apple, Inc. iPhone iOS smartphone or an Android smartphone for at least one month (such that they are familiar with basic operations of the mobile platform)
- Willing to sign the Informed Consent Form

Exclusion Criteria

- Prior experience with a study sponsored by Carrot Inc.
- Pregnancy

8.4 SUBJECT RECRUITMENT

Subjects will be recruited in the United State by a clinical research recruiter and/or through advertisement at outdoor locations (i.e. flea markets, outside of movie theaters, shopping malls, train stations, stores that sell cigarettes), print media (i.e., local newspapers, billboards), and web media (e.g. Craigslist, Facebook, Task Rabbit, Google Ads) [redacted]. Potential subjects will convey their interest in participating in the study by calling or emailing study personnel using the contact information provided in the recruitment materials, or responding to outreach from the clinical recruiter.

All study participants will undergo a screening call where they will be asked questions to confirm study eligibility. During this call, study personnel will inform the potential subject 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 scheduling, and if so, study personnel will schedule the subject for a test session. At the test session, an Informed Consent Form [redacted] will be signed prior to participation.

8.5 SUBJECT STIPEND

Participants will be compensated $100 in the form of a Visa Gift card for the test session lasting approximately 60 minutes. Participants will be compensated at the end of their study session.

8.6 SAMPLE SIZE AND JUSTIFICATION

Per FDA Guidance (US Food and Drug Administration (FDA), 2016) and HE75 – Human factors engineering – Design of medical devices (ANSI/AAMI, 2013), a Usability Validation Study should include at least fifteen (15) participants of each user group. Since

the Pivot Breath Sensor has one (1) user group and no critical tasks were identified, this study will include up to 15 subjects. This sample size is expected to provide adequate data to assess the human factors and usability of the Pivot Breath Sensor.[1]

8.7 STUDY ARTICLES

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

- Pivot Breath Sensor
- USB charging Cable
- Replaceable Mouthpiece
- Quick Start Guide [redacted]
- User Manual (available on an iPad)

In addition, the testing room will be equipped with electrical outlets and a charging cube.

8.8 EQUIPMENT AND MATERIALS

- A pre-set Pivot Breath Sensor with example CO breath samples, or a CO Log Print Out
- Printed prompt cards for the participant to reference during each task
- Timer or clock
- Video recording equipment
- Camera
- Post-it notes
- Quick Start Guide for Observer/ Moderator
- User Manual (printed) for Observer/ Moderator
- Electronic Surveys
- Case Report Forms

A full list of equipment and materials used during the study will be recorded in the report.

8.9 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. No in-person training is formally offered to Pivot Breath Sensor users. A Quick Start Guide and package labeling is included with the device and an online User Manual is also available to aid the user. All of these items will be accessible to the study participant plus a phone and a phone number within the labeling material to contact technical support. Since in-person training will not be formally offered to all users who purchase the Pivot Breath Sensor, in-person training will not be included in this study. Study participants will have access to the aforementioned materials. Any instance of participants referring to the User Manual,

[1] In previous usability testing, two subgroups of users used a similar, predecessor breath sensor, with one subgroup including 18 to 49-year-olds, and with the other subgroup including 50 to 80-year-olds. User performance was compared between the two subgroups, and no statistical difference was identified between the two cohorts for any of the tasks, except for accessing the CO Breath Sensor Frequently Asked Questions (FAQs). Based on previous testing, it was concluded that age is not significant enough of a contributing factor to require two separate user profiles in usability validation testing for this product. As such, a single user group consisting of participants with a range of ages will be tested as part of this study.

Quick Start Guide or packaging during the study will be recorded.

While participants will have the User Manual, Quick Start Guide and packaging available to them at any point during the study, they will not be asked to read instructions (except during the knowledge questions covered in the User Documentation Assessment – see Section 11.2) or use any of the forms of training available.

8.10 TEST ENVIRONMENT

The study will be performed in an office building conference room or office.

8.10.1 Location testing will be performed:

The location of testing will either be at the Carrot Inc. office [redacted] or equivalent. For example, office space may be rented to be nearer to test subjects.

8.11 STUDY PERSONNEL

The study team members will be trained by reading the study protocol and reviewing the case report forms. The study team members will have full training on the operation of the study devices.

The following roles will be fulfilled by Carrot Inc. employees and consultants during the study:

- Study Moderator – Responsible for moderating the study, delivering instructions (as needed) and ensuring that participants progress from one use scenario to the next, and asking questions to probe about observed use errors and close calls.
- Study Facilitator – Responsible for organizing the simulated environment, study articles, equipment, and required documentation (e.g. informed consent form, non-disclosure agreements).
- Study Observer(s) – Responsible for taking notes during the study sessions and documenting key events of the study as they occur.
- Technical Support – Responsible for troubleshooting system issues and recording bugs in the case there is a system issue during the study session.

One person may fulfill more than one role.

8.12 IRB OVERSIGHT

This study will be conducted under IRB oversight.

9. STUDY PROCEDURE

At the beginning of the test session, subjects will have ample time to read the Informed Consent Form (ICF) and the opportunity to ask questions. The subject will sign the ICF before participating in this study. Once signing the ICF, the subject will be given a unique identifier to protect subject privacy. Subjects may choose to exit the study at any time. They are not required to complete the study if they choose to stop.

Study participants will self-train on how to use the study device using only the available study Pivot Breath Sensor device labeling, including product packaging and Quick Start Guide. A technical support line provided in packaging/Quick Start Guide and the User

Manual will be available should a participant request them. These labeling materials will be available to study participants at any point during the study. Study participants will not be asked to read instructions or use any of the forms of training available except during the knowledge questions covered in the User Documentation Assessment – see Section 11.4. Study personnel will refrain from answering questions on how to use the study device during the study.

Once the study participant has completed the self-training on the Pivot Breath Sensor, they will be asked if they feel ready to proceed with submitting a breath sample. If a participant indicates they do not feel ready, they will be asked to do what they would normally do at home to prepare to use the product and to let the test administrator know when they are ready to submit another sample.

When the participant indicates readiness to provide a breath sample, he/she will be instructed to proceed to provide one breath sample using the study device. After providing this breath sample, the subject will be asked to interpret his/her breath sample result followed by interpretation of other possible breath sample results and the first set of subjective questions. The subjective questions will address the subject's feedback on how giving a breath sample went for them. At which point, the participant will be asked to change the mouthpiece. An optional breath sample may be requested by the moderator followed by interpretation of his/her breath sample result.

Upon completion of these breath sample(s), participants will be asked for subjective feedback, if they experienced difficulty, concerns, or moments of hesitation while using the product, and if they have safety concerns regarding the product or its labeling. Next, they will be assessed for their newly learned knowledge of the device (focused on if CO is "good or bad for you") and their ability to find and understand information in the product labeling. This is followed by obtaining the participants additional subjective feedback and rating scales.

10. DATA COLLECTION

Study personnel will collect information about the participant including

- Age
- Gender
- Race/ethnicity
- Vision
    - Wear glasses?
    - Color blind?
- Hearing
    - Hearing issues?
    - Use a hearing aid?
- Type of smartphone participant uses (iPhone or Android)
- Number of years smoking
- Number of quit attempts over the past 12 months
- Number of cigarettes currently smoked per day

- Smoking history in the past 24 hours
    - Number of cigarettes smoked
    - Time of last cigarette
    - 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
- Attitudes towards smoking
    - Desire to quit
    - Readiness to quit
    - Confidence to quit
    - Perceived difficulty of staying quit
- Current smoking cessation medications
- Participation in a smoking cessation program
    - Past
    - Present
- Breath sensor use (past)
    - Use of CO breath sensors in the past
- Breath sensor use during the study session
    - Model#/Lot# of breath sensor
    - CO measurements

11. TECHNICAL APPROACH AND STUDY DESIGN

11.1 HUMAN FACTORS AND USABILITY ACCEPTANCE CRITERIA

Each use scenario and user documentation assessment test case will be attributed one of the following assessments for task success:

- Successful: User is able to complete the task safely and effectively. If the user does not complete the task on first try but self-corrects to complete the task without moderator direction or assistance, the task completion may be considered Successful.
- Difficulty: User is able to complete the task safely and effectively, but has significant hesitation or challenges while completing the task. If the user does not complete the task on first try but self-corrects to complete the task without moderator direction or assistance, the task completion may be considered Difficulty.
- Close Call: User is able to complete the task safely and effectively, but performs it in a way that presents the potential for user harm (i.e. near-miss).
- Unsuccessful (Use Error): User is unable to independently complete the task or does not complete the task safely and effectively. Includes instances in which users are unable to complete the task and as a result require study moderator assistance. Instances in which the user self-corrects without requiring moderator assistance do not qualify as unsuccessful.

- Did Not Perform: User does not complete the task for safe and effective use of the device.

At any time, the moderator may remind the participant of the scenario of the testing and the frame of mind they should strive for. A possible reminder may be "Continue to do your best…as a friendly reminder imagine that you are home, that we are not here, and that you just bought this product from the store." Any instance of study moderator assistance will be noted and assessed depending upon the extent of the assistance provided.

The Pivot Breath Sensor Use FMEA governs Acceptance Criteria for the Pivot Breath Sensor Usability Validation Study. Each hazard-related use scenario observed during usability validation testing will be documented and assessed for risk acceptability as defined in the Use FMEA.

In the case that a hazard-related use scenario is concluded to have an acceptable risk profile per the Use FMEA, its associated test case is considered to "pass." In the case that a hazard-related use scenario is concluded to have an unacceptable risk profile per the Use FMEA, its associated test case is considered to "fail." In the case of a failed test case, further risk mitigation and usability evaluation would be required. In the case that further risk mitigation is not possible, a risk-benefit analysis would be documented.

Since there are no critical tasks associated with this product, there is no pre-identified task-specific acceptance criteria related to this study; no use errors were identified that could lead to serious harm. Overall, user performance on each task will be monitored for unforeseen use errors that could lead to serious harm.

11.2 STUDY SESSION FORMAT

Each study session will have the following format:

1. Introduction
2. Simulated Use
3. Subjective Feedback
4. Knowledge Tasks
5. User Documentation Assessment
6. Subjective Feedback and Rating Scales

Following a brief introduction each participant will undergo a study session lasting about 60 minutes. The study session will comprise use scenarios, knowledge tasks, user documentation (User Manual and Quick Start Guide) assessment, subjective feedback and rating scales. In addition to the subjective feedback obtained during the defined sections below, subjective feedback may be collected during the use scenarios, knowledge tasks, and User Documentation assessment to inform root cause analysis.

The use scenarios included in the study consider inputs from risk management documentation (Pivot Breath Sensor Use FMEA) to test mitigations to device use (operation) related hazards. Each use scenario is expected to take up to 5 minutes (most will take 2-3 minutes). The use scenarios are listed in Table 2.

The study session will be conducted as a simulated use study where each participant will have access to the study article and will be monitored while performing the use scenarios. Each use scenario is monitored for difficulties, close calls and use errors. The use scenarios will allow for a detailed and focused assessment of the different components of the Pivot Breath Sensor set-up and use.

Table 2. Use Scenarios for Usability Validation

ID	Use Scenarios
1	[redacted]
2	[redacted]
3	[redacted]
4	[redacted]
5	[redacted]ple
6	[redacted]

-

11.3 USE SCENARIOS

11.3.1 Use Scenario 1: Self-Selection

- Configuration:

  The study moderator presents the participant with the Pivot Breath Sensor device package.

- Prompt:

  Take a moment to examine the package. Now I will ask you some questions about whether this product is appropriate for different types of people. (Note: [redacted])

  1. [redacted]
  2. [redacted]
  3. [redacted]

11.3.2 Use Scenario 2: Start-up device

- Configuration:

  The study moderator presents the participant with the Pivot Breath Sensor device package.

- Prompt:

  Here is a new Pivot Breath Sensor that has never been used. Please imagine you just bought this product from the store. Given that you just purchased it, you can take as much time as you need to familiarize yourself with the product. Pretend that we are not here. Please start using the product as you normally would at home when you are ready. Feel free to take as much time as you need.

  (If user does not begin using device after familiarization period) Please proceed with using the product.

  (If the user states they would not use or purchase this product) Let's assume you were given this product to use as a requirement of a smoking cessation program. Take as much time as you need to familiarize yourself with the product. Please start using the product when you are ready.

- Tasks:
  - Open the Pivot Breath Sensor packaging
  - Complete Breath Sample

- Prompt:

  How did that go for you?

11.3.3 Use Scenario 3: Interpret your results – Part 1

- Prompt:

  Please walk me through your test results. What does each result mean?

  ➢ [redacted]

- Tasks:
  - Access the CO Log
  - Understand results from the breath tests

  Note: This Use Scenario may be continued for interpreting results for Use Scenario 5. (See section 11.3.5 below.)

  Expected Response:

  For green value:

- [redacted]

  Or,

- [redacted]

[redacted]

Or,

- [redacted]

For orange value:

- [redacted]

Or,

- [redacted]

Or,

- [redacted]

For red value:

- [redacted]

Or,

- [redacted]

Or,

- [redacted]

11.3.4 **Use Scenario 4: Interpret more results**

- Configuration:

  The study moderator provides Device with at least three (3) past CO readings having all of the colored CO ppm ranges for the participant to interpret (red, green orange) so participant can interpret colored ppm ranges he/she did not obtain from his/her own breath sample(s).

  - Study moderator and/or observer to monitor participant [redacted]

- Prompt 1:

  What does it mean if the result of a person's breath test looks like this? (Moderator points to a green, orange, or red result. An attempt will be made to evenly distribute the order the colors are presented across all groups by counterbalancing.

Counterbalancing scheme will be provided in the final report. Moderator will only ask about results that were not previously covered in Scenario 3)

Expected response: See 11.3.3 response

- Prompt 2:

  What does it mean if the result of a person's breath test looks like this? (Moderator points to a green, orange, red or gray result, counterbalanced across participants. Moderator will only ask about results that were not previously covered in Scenario 3)

  Expected response: See 11.3.3 response

- Prompt 3:

  What does it mean if the result of a person's breath test looks like this? (Moderator points to a green, orange, red or gray result, counterbalanced across participants. Moderator will only ask about results that were not previously covered in Scenario 3) Note that Prompt 3 will be asked unless all result colors were previously covered.

  Expected response: See 11.3.3 response

- Prompt 4:

  [redacted]

11.3.5 Use Scenario 5: Use a new mouthpiece and optionally submit a breath sample

- Prompt:

  Please replace the mouthpiece on the Pivot Breath Sensor.

- Prompt (Optional)

  Please replace the mouthpiece on the Pivot Breath Sensor and submit a breath sample.

  - Study moderator and/or observer to monitor for lightheadedness while providing a breath sample.
  - Study moderator and/or observer to monitor and record the number of seconds of participant's breath hold starting from inhalation.

- Tasks:
  - Assemble the Pivot Breath Sensor with the new mouthpiece
  - Submit a breath sample (Optional)

- Follow up prompt (Optional):

  (If participant does not switch out mouth piece before submitting the new sample): Please use a new mouthpiece.

- Study observer confirms breath sample taken 3 to 5 minutes from last successful breath sample and records the time of the sample submission.

- Prompt:

  How did that go for you?

  (Next prompt is a Continuation from Use Scenario 3 above)

- Prompt:

  Please walk me through your test result. What does this result mean?

  - [redacted]

- Tasks:
  - Access the CO Log
  - Understand result from the breath test

  Expected response: See 11.3.3 response

11.3.6 Use Scenario 6: Charge the Pivot Breath Sensor

- Prompt:

  Please proceed to charge the Pivot Breath Sensor.

- Tasks:
  - Connect the USB charging cable
  - Charge the device

11.3.7 Subjective Feedback Part 1

- Prompt:

  Were there any points during this portion of the study that you experienced difficulty or had concerns about the product?

- Prompt:

  Did you experience any moments of hesitation while using the product?

- Prompt:

  Do you have any safety concerns regarding the product or labeling?

- Prompt (Optional):

  Did you hold your breath when you submitted the recent samples?

11.3.8 Knowledge Tasks

- Prompt:

[redacted]

- [redacted]

[redacted]

[redacted]

Upon completion of the use scenarios and knowledge tasks (described above), a user documentation assessment session (described below) will be performed followed by a final subjective feedback session to better inform the safety and efficacy of the Pivot Breath Sensor.

11.4 USER DOCUMENTATION ASSESSMENT

Participants will never be asked to refer to the labeling during simulated use scenarios. Any instance of participants referring to the labeling during the simulated use scenarios will be recorded and assessed.

After completion of the simulated use scenarios, the user documentation (Quick Start Guide, Packaging, and User Manual) will be tested for ease of use and clarity of content. Each user documentation assessment session will have test cases to assess the findability and the interpretation of knowledge task data found in the User Documentation. Participants will be asked to find and/or interpret pieces of essential information. Participants will demonstrate understanding through verbal explanation. The questions and expected answers for the user documentation assessment are found in Table 3.

Table 3. User Documentation Assessment

User Documentation Task ID	User Documentation Assessment Tasks	Question	Participant Response
[redacted]			
1	[redacted]	[redacted]	[redacted]

		[redacted]	
2	[redacted]	[redacted]	[redacted]

			[redacted]
3	[redacted]	[redacted]	[redacted]

			[redacted]
4	[redacted]	[redacted]	[redacted]
5	[redacted]	[redacted]	[redacted]

6	[redacted]	[redacted]	[redacted]
7	[redacted]	[redacted]	[redacted]
[redacted]			
8	[redacted]	[redacted]	[redacted]

			[redacted].
9	[redacted]	[redacted]	[redacted]
10	[redacted]	[redacted]	[redacted]
11	[redacted]	[redacted]	[redacted]
12	[redacted]	[redacted]	[redacted].

13	[redacted]	[redacted]	[redacted]
[redacted]			
14	[redacted]	[redacted]	[redacted]
15 (Ask only if participant did not state both expected answers)	[redacted]	[redacted]	[redacted]

11.5 SUBJECTIVE FEEDBACK AND RATING SCALES

In addition to the subjective feedback obtained periodically throughout the study session,

additional subjective feedback may be collected during the use scenarios and user documentation assessment to inform root cause analysis.

Following the user documentation assessment, the participants will be subjected to rating scale questions to rate the ease of use of the device, the clarity of the user documentation and their ability to understand and interpret the test results.

11.6 METHODS FOR CAPTURING USE ERRORS

During each study session, observer(s), and moderator(s) will observe for difficulties, use errors and close calls that could inform modifications to the Pivot Breath Sensor Use FMEA. The study moderator will also ask probing questions, at the end of the session, to reveal close calls that were not conveyed through observation. All use errors and difficulties will be followed with questions to identify how and why the participant believes they occurred. New, unforeseen use-related hazards will be assessed for risk acceptability and added to the Pivot Breath Sensor Use FMEA.

The study team will include subjective assessments by participants for any observed use-related issues that could potentially result in harm to the user.

Users will perform tasks independently and in a natural manner, without guidance, coaching, praise, or critique from the test facilitator or moderator. Users will not be allowed a "second chance" to perform a task correctly after a failure. That is, if an irreversible safety or efficacy issue is observed in which a user would not normally have a "second chance" to resolve the issue, then any subsequent attempts to complete the task will serve as input only for continuous usability improvement purposes. In instances in which an irreversible safety or efficacy issue is not observed and the user would normally have additional chances to resolve this issue, any subsequent attempts by the user to complete the task will be taken into consideration when attributing an assessment (i.e. successful, difficulty, unsuccessful, close call, did not perform) to the task.

The study team will ensure participant feedback is documented throughout the session, as well as any protocol deviations. Prior to the end of the test session, the study team will review all data sheets for completeness and pursue additional information or clarification as needed. The study team will then inform participants when the test session is complete.

The study team will scan the data sheets and save them to a secure study file. All members of the study team will be familiar with the device operation to be qualified to administer the test and assess participant performance with the device. The study team will write the summary report.

12. STUDY RESULTS

12.1 DATA COLLECTION AND CONFIDENTIALITY

Subjects will be assigned a unique subject ID which will be used for data collection. Data collection will take place on paper or electronic case report forms (CRFs) completed by the study team and study subjects. CRFs will be reviewed by the study team prior to the end of the study session to ensure completeness and then stored in a secure filing cabinet at the end of the day with access 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 5 years.

12.2 ANALYSIS

The study will utilize paper-based data entry procedures, subject to audit per Carrot Inc. standard operating procedures.

12.2.1 Human Factors and Usability

The data sheets will be printed and used to facilitate note taking and the capture of close calls and use errors that are observed during each session. Data collection and analysis will include both objective data and subjective data collected via test cases that are provided to the user.

Objective data will include:

- Participant answers to use scenarios and user documentation assessment test case questions assessing user comprehension.
- Study team assessment by use scenario, based on pre-determined acceptance criteria (see sections 11.1 and 11.4).

Subjective data will include:

- Participant feedback on ease of use, understandability, and possible improvements.
- Study team feedback on any issues with participant comprehension or ability to complete user tasks.

In the case that a problem or a use error is observed, the study moderator will probe for root cause and record the participant's assessment of safety and risk acceptability. This subjective input of risk acceptability will inform the final assessment and conclusion of risk acceptability made by the study personnel during data analysis. Both observational data and subjective input will facilitate identification and understanding of the root causes of use errors or difficulties that occur.

As needed, photo and video recordings may be implemented during the study to facilitate post-study analysis of user-feedback, use errors, and close calls.

More than one study observer may record data using the data sheets. As a result, data may differ between note-takers. After the session is complete, the observer(s) and moderator(s) will meet to discuss any difficulties, use errors, or close calls. Data will be compiled in a spreadsheet, and study team may re-assess ratings based on further analysis, video review, or discussion (e.g. a "Difficulty" may be re-assessed as a "Close Call" after the data sheets are complete). Hand-written data will not require amendment based on the re-assessment. In any instances where ratings are modified, a comment will be made in the cell in the spreadsheet or a log will be otherwise recorded to indicate that each change was agreed upon by the study personnel.

12.3 REPORT

A final report will be issued upon completion of testing, allowable in PowerPoint format, and will include the following:

- Report must include observations of task performance and occurrences of use

errors, close calls, and use problems.

- Report must include feedback from interviews with test participants regarding device use, use errors and problems (as applicable).
- Report must include description and analysis of all use errors and difficulties that could cause harm, root causes of the problems, and implications for additional risk elimination or reduction.
- Report must include testing details such as description of products tested and identification numbers.
- Report must identify staff members who tested and evaluated/inspected samples. Test date(s) must be identified.
- Report must identify any deviation from the protocol, and any anomalies in sample testing. Justification and approval of deviation by Carrot Inc. must be documented.
- Report must include test results section and must identify any changes to the testing samples.
- Report must reference completed data sheets. All data sheets will be signed and dated.
- Report must be signed by the primary investigator or study team designee. It must also be reviewed and approved by the study team.

12.4 DEVIATIONS FROM PROTOCOL

To be determined by the study team during usability 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.

12.5 RECORD RETENTION

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

13. CONFLICTS OF INTEREST

The following conflicts of interest are noted:

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

The investigators hold the following positions:

- [redacted] Sr. Director of Clinical and Medical Affairs (senior management officer)
- [redacted] Director, Clinical Affairs
- [redacted] Senior Clinical Research Associate, Clinical Affairs

These conflicts of interest are mitigated by the following:

- The risk profile of the study, specifically, that there are no 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 done under the guidance of trained study personnel. Study participants will be able to indicate how they are feeling and if they would like to continue or discontinue giving breath samples.

- 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 usability of the Pivot Breath Sensor in intended users and then use this data to 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.

14. [redacted]

15. **LITERATURE REFERENCES**

16. **DOCUMENT REVISION HISTORY:**

Rev. A	Original Protocol (Pivot Breath Sensor Usability Study)