

# Carbon Monoxide (CO) Breath Sensor System (COBSS) FP-20021

**Draft User Manual** 

### **Contact Information:**

In case of medical emergency, call 911.

For assistance and support, call the Carrot Sense help-line: 1-XXX-XXXX-XXXX

Manufactured For: Carrot Sense, Inc. 1600 Seaport Blvd, Suite 150 Redwood City, CA 94063 U.S.A. www.carrotsense.com

We advise that you read this entire manual before operating the device.

# **Table of Contents**

1	Sys	tem O	verview	1	
2	Bac	kgroui	nd Information (Smoking and Breath Carbon Monoxide)	1	
3	Ind	ication	s for Use	1	
4	Cor	ntraind	lications	1	
5	Wa	rnings		1	
6	Pre	cautio	ns	1	
7	Not	tes		2	
8	Cor	ntents		2	
9	CO	Breath	n Sensor	2	
	9.1	Charg	ging the CO Breath Sensor	2	
	9.2	Clear	ning	3	
	9.3	Straw	/S	3	
10	) Bre		nsor Application		
	10.1		ng to Smartphone		
	10.2		ng Started		
	10.3		nitting a Breath Sample		
	10.4		og		
	10.5		reath Sensor Settings		
	10.	_	Connection Status, Sync Status and Battery Life		
		5.2	Reminders, Vibration, Volume		
	10.		Utilities		
		•	December 2017 december 2017		
	10.		Breath Test Video Tutorial		
	10.		Using Your Breath Sensor		
	_	6.3	About		
	10.	_	Legal		
11			pecification		
12	•				
13			s and Symbols		
14	<b>U</b>				
	5 Frequently Asked Questions				
16					
17	' Wa	rrantv	, Return Goods Policy	. 12	

## 1 System Overview

The Carbon Monoxide (CO) Breath Sensor System (COBSS) consists of a personal mobile breath sensor (CO Breath Sensor) capable of measuring a user's level of CO in their exhaled breath and a Breath Sensor App (BSA) for smartphones which displays the exhaled breath CO value to the user.

## 2 Background Information (Smoking and Breath Carbon Monoxide)

Smoke from a burning cigarette contains high levels of carbon monoxide or CO (a by-product of combustion). When cigarette smoke is inhaled into the lungs, CO enters the bloodstream. Over time, the CO is slowly released in the exhaled breath. The level of CO in exhaled breath can be measured using the CO Breath Sensor and the Breath Sensor App, which together, make up the CO Breath Sensor System or COBSS.

The amount of carbon monoxide in the exhaled breath of a smoker is related to the intensity, frequency, technique and amount of smoking behavior. Simply put, the more one smokes, the higher their exhaled breath CO levels tend to be. When a smoker stops smoking (smoking cessation), their exhaled breath CO levels drop within a few days to values seen in non-smokers. Exhaled breath CO readings have been shown to be useful for smokers who are trying to quit smoking (smoking cessation), as the personal CO information provides educational feedback regarding their smoking exposure.

#### 3 Indications for Use

The Carbon Monoxide Breath Sensor System is a breath carbon monoxide monitor intended for single-user use in smoking cessation programs.

#### 4 Contraindications

There are no known contraindications at this time.

## 5 Warnings

• Low levels of CO do not indicate that it is safe to increase your smoking. Smoking is harmful to your health and any amount of smoking is unsafe.

#### 6 Precautions

- Sit down while doing breath samples. Holding your breath and then blowing into the device may cause some users to become lightheaded, which may lead to falls.
- Do not strain while doing a breath sample, as this may cause lightheadedness, which may lead to falls.

- When taking a deep breath in to do a breath sample, do not take this breath in through the straw or CO Breath Sensor.
- Do not use the COBSS while operating any type of vehicle or machinery as you may be distracted from the operation.
- After cleaning straws with soap and water, ensure they are dry inside and out before using.
- The straw is a small part and may be a choking hazard. Keep away from children under 3 years.
- Do not use any alcohol containing products, such as alcohol wipes or gel, on the CO
  Breath Sensor as they may interfere with the function of the CO Breath Sensor and CO
  values.
- Do not submerge the CO Breath Sensor in water or other liquids.

#### 7 Notes

- Do not use in cases of suspected carbon monoxide poisoning. Call 911.
- Do not use in cases of suspected smoke inhalation (e.g. from a fire). Call 911.
- Do not use the CO Breath Sensor while plugged in for charging as it will not function.

#### 8 Contents

CO Breath Sensor packaging includes:

- CO Breath Sensor with straw inserted
- 7 straws in a bag
- Micro USB charging cable
- User Manual (this document)

#### 9 CO Breath Sensor

The CO Breath Sensor is portable, battery-powered, and small enough to be conveniently carried by the user (e.g. pocket, purse, backpack).

#### 9.1 Charging the CO Breath Sensor

Insert the micro USB plug into the CO Breath Sensor. Connect the cable to a USB charging port on a computer or USB charging cube. It takes 1 to 2 hours to fully charge. When the CO Breath Sensor is plugged in:

- LED pulses orange to indicate charging
- LED turns solid green to indicate fully charged
- Device will NOT function to receive breath samples
- Device will provide notifications for sampling (if enabled)

Figure 1. CO Breath Sensor



#### 9.2 Cleaning

Cleaning is optional. If you choose to clean, use a lightly damp clean cloth to wipe down the outside CO Breath Sensor. Do not allow water to enter any openings in the device.

#### 9.3 Straws

Straws are reusable and may be cleaned. To clean, wash with mild hand soap and warm water and allow to completely dry before use. Replace as necessary.

## 10 Breath Sensor Application

#### **10.1** Pairing to Smartphone

See Product Specifications for compatible smartphones to pair with your CO Breath Sensor. Follow these steps to pair:

- a. On your smartphone, download and install the My Breath CO application from the Apple App Store (iOS) or Google Play (Android).
- b. On your smartphone, turn Bluetooth "on".
- c. Open the My Breath CO application. You will see a welcome screen followed by a Breath Sensor Pairing animation.
- d. Your smartphone will look for any available, ready-to-pair, CO Breath Sensors.

- e. To make your CO Breath Sensor available for pairing, press and hold the CO Breath Sensor button until the LED flashes cyan (light blue), then release the button.
- f. If your CO Breath Sensor LED flashes green, tap Confirm on the screen to complete the Bluetooth pairing process.
- g. If your CO Breath Sensor is NOT flashing green, wait to select the Try Again button and start again.

#### 10.2 Getting Started

After successful pairing, you will be directed to the Getting Started page, where you will watch the Breath Test Video Tutorial. This video provides instruction about how to use your CO Breath Sensor to measure the amount of CO in your breath. You must watch this video in order to continue further into the app.

After viewing the Breath Test Video Tutorial, you will go to an interactive tutorial called YOUR Guided Breath Test (GBT). In YOUR GBT, you'll learn how to submit a breath sample by following interactive on-screen prompts.

Before using YOUR GBT, make sure your sensor is fully charged and in your hand, and make sure the air temperature is not too cold or too hot (between 40°F and 90°F) so that the sensor can fully detect when you start and stop blowing.

YOUR GBT will guide you through the steps and timing of taking a deep breath in, holding it, and then blowing gently into the CO Breath Sensor.

- a. The sensor and app determine if you have provided an adequate breath sample:
  - i. If yes, you will see a "success" screen with a smiley face; tap View Results to view your results on the CO Log screen.
  - ii. If the submitted sample was not adequate, you will be asked to repeat the Guided Breath Test. Reasons for inadequate breath sample include blowing too soon, not long enough, or starting too late.







Inadequate breath sample

b. You may repeat the video tutorial or Guided Breath Test as often as you like by going to the Help screen.

#### 10.3 Submitting a Breath Sample

- a. Insert a straw in the inlet of CO Breath Sensor.
- b. Press and hold the button until you hear a beep and the LED starts flashing blue. Take a deep breath in and hold it, and release the button. You will hold your breath for 10 seconds.

NOTE: If you cannot hold your breath for a full 10 seconds, you may begin holding your breath a few seconds after the first notification beep. In this case, you will hold your breath for less than 10 seconds. Your breath CO (ppm) results may be slightly lower if you do not hold your breath for the full 10 seconds.

- c. After about 8 seconds, you will hear the first of 3 beeps to prepare you to blow into the sensor.
- d. Upon the third beep, gently blow into the straw and CO Breath Sensor for about 12 seconds or until you exhaust your entire breath.
- e. After you stop blowing, the LED will flash either green or red.

**Table 1. LED Light Indications After Breath Sample** 

LED Light	Description		
Green	You provided an adequate breath sample and your data was saved		
Red	<ul> <li>Your breath sample was not adequate, which may be due to:</li> <li>1. You started blowing into the sensor before the third beep (too early)</li> <li>2. You waited too long after the third beep before starting to blow (too late)</li> <li>3. You did not blow long enough (minimum 6 seconds) (not long enough)</li> </ul>		

- f. The CO values and the date and time of the breath sample are saved on the CO Breath Sensor until it syncs with your smartphone.
- g. Syncing occurs automatically when the app is open and is able to connect to the CO Breath Sensor (sensor is near-by, smartphone Bluetooth is on, sensor is charged).
- h. If you need to cancel a breath test at any time after initiating, hold down the Breath Sensor button for 3 seconds (you will feel a slight pulse to confirm it cancelled, and the LED will stop flashing).

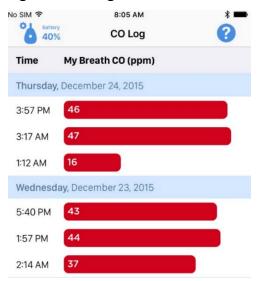
Figure 2. Doing a Breath Sample



#### 10.4 CO Log

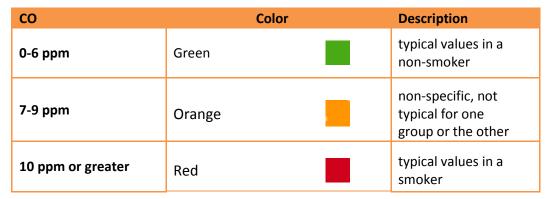
- a. The CO Log is the default screen when you open the app and is where you can view your breath sample results.
- b. In the CO Log, you can scroll up and down to view each of your CO Breath sample results by date and time.

Figure 3. CO Log



c. Your CO breath sample values are presented in parts per million (ppm) within color coded bars (See **Error! Reference source not found.**). Higher numbers represent higher levels of CO in your breath.

Table 2. Color Coded Bars according to Breath CO Levels (ppm)



d. The length of each bar relates to the CO value, as well, to show you the relative value of each sample. Longer bars indicate a higher level of CO than shorter bars.

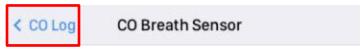
- e. Maximum bar width = 50 ppm; any value above 50 ppm is shown as the 50 ppm bar length for ease of viewing and is marked with a white arrow.
- f. From the CO Log, you can go to the CO Breath Sensor screen by tapping the settings (gear and sensor) icon in the CO Log header. You can also go to the Help screen by tapping the question mark icon in the CO Log header.

Figure 3. Icons to go to CO Breath Sensor (left) and Help (right) Screens from CO Log



g. To return to the CO Log from other pages (CO Breath Sensor and Help screens), tap CO Log in the upper left corner.

Figure 4. Icon to Return to CO Log



#### 10.5 CO Breath Sensor Settings

The CO Breath Sensor page allows you to view your CO Breath Sensor status (Connected, Syncing or Not Connected), last sync, and battery status. It also allows you to set reminders and perform other functions in utilities. This page can be accessed by tapping the settings (gear and sensor) icon within the CO Log header.

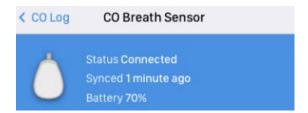
Figure 3. Icon to go to CO Breath Sensor Screen



#### 10.5.1 Connection Status, Sync Status and Battery Life

The connection status will either be Connected, Syncing or Not Connected. Last sync is shown in time (min, hours) and battery life is shown as a "%".

Figure 4. Connection Status, Sync Status and Battery Life



## 10.5.2 Reminders, Vibration, Volume

You may use the Reminders function to help you remember to submit breath samples throughout your day. Reminders must be toggled to green (on) to access. When reminders are on, the CO Breath Sensor will deliver notifications. These notifications take the form of a flashing LED, beeps and/or vibration. You may modify the following reminder settings:

- a. Time of the First Reminder of the day (default 7 am)
- b. Time of Last Reminder of the day (default 11 pm)
- c. Reminder time interval (default every 1 hour)
- d. Type of reminder
  - i. Vibration (Off, Low, Medium, High) (default Medium)
  - ii. Volume of beep (Off, Low, Medium, High) (default Medium)
- e. A separate control is provided for the volume of the beep prompts that occur when you submit a breath test (off, low, medium, high) (default is medium)

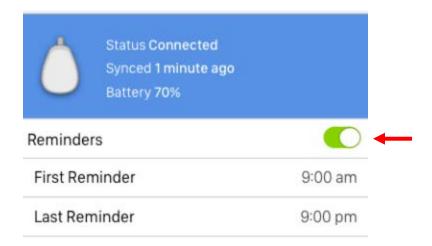


Figure 5. Reminders Activated (green = on)

#### 10.5.3 Utilities

Use Utilities to access additional functions:

- a. Sync Now
  - Manually syncs the CO Breath Sensor with the smartphone.
- b. Ring Sensor

Make your CO Breath Sensor "ring". Helpful if you have misplaced it. Sensor must be connected to the smartphone for the sensor to ring.

#### c. Forget Sensor

Unpair the connected sensor. After unpairing, you can pair with a new sensor.

#### 10.6 Help

The Help Menu provides access to the video tutorial and Guided Breath Test, described earlier in this User Manual, as well as a frequently asked questions section.

Additional information about the CO Breath Sensor System is located under About within the Help page. This page can be accessed by tapping the question mark icon within the CO Log header.

Figure 6. Help Icon



#### 10.6.1 Breath Test Video Tutorial

View a video on how to properly give a breath sample

#### 10.6.2 Using Your Breath Sensor

a. Guided Breath Test

Step by step instructions to complete a breath sample.

b. Frequently Asked Questions

Responses to common questions.

#### 10.6.3 About

c. Email Your CO Data

Email a copy of your CO log data (.csv file).

d. <u>Send Report to Technical Support</u>

Notify Carrot Sense of any technical issue you might be having.

e. Breath Sensor ID

The CO Breath Sensor identification.

f. Firmware Version

The version of the firmware on the CO Breath Sensor.

g. App Version

The version of the app installed.

#### 10.6.4 Legal

This section contains Carrot Sense's Terms of Service and Privacy Policy.

## 11 Product Specification

**Table 3.Product specifications** 

Description	
Carbon Monoxide Concentration range (ppm)	0-100
Detection Principle	Electrochemical sensor
Repeatability	±10%
Any known interferants	TBD
Power	Lithium battery
Battery life	7 days per charge
Operating Temperature	40°F-85°F for breath tests
	40°F-104°F for all other functions
Operating Humidity range	10-90% non-condensing
Sensor life	3 years
Sensor Drift	5% per year
Weight	TBD
Dimensions	2.5x4.5x6.0cm
Materials	Device enclosure: Polycarbonate
	Straw: Polypropylene
Power supply specifications	5Vdc 250mA
Breath Sensor app is compatible with:	
iPhone (x, y, z) with iOS XX or later	TBD
Android (x, y, z)	TBD
Bluetooth type	Bluetooth low energy (BLE)

# **12** Definitions and Symbols

**Table 4.Definitions** 

Term	Definition
СО	Carbon Monoxide, a by-product of combustion
ppm	Parts per million

**Table 5. Symbols** 

Symbol	Definition	
	Manufacturer	
	Use-by date	

Symbol	Definition
LOT	Batch code
REF	Catalog Number
	Do not use if package is damaged
$\bigcap_{\mathbf{i}}$	Consult instructions for use
USPRS USPRS	Single User Only
<b>†</b>	Type BF Applied Part
QTY	Quantity
FCC ID	Federal Communications Commission certification identification number

## 13 Troubleshooting

- If your paired CO Breath Sensor is not syncing with your smartphone, make sure your CO Breath Sensor is fully charged and is near the smartphone.
- If CO Breath Sensor is showing "Not Connected" in the CO Breath Sensor screen, make sure that Bluetooth is activated on your phone and that the CO Breath Sensor is charged. If paired, the CO Breath Sensor and application will sync automatically.

## **14 Frequently Asked Questions**

• What if I can't hold my breath for the 10 seconds prior to blowing into the CO Breath Sensor?

Try waiting a few seconds after being prompted to take a deep breath in. This shortens your breath hold time by a few seconds. As a result, the CO ppm readings may be lower than if you had held your breath for the full 10 seconds.

How can I review how to give a breath sample?
 Go to the Help screen and repeat the video tutorial and/or Guided Breath Test.

## 15 Service/Maintenance

No service or maintenance is to be performed on the device by the user.

## 16 Warranty, Return Goods Policy, Disposal Instructions

TBD

The device contains a lithium battery that needs to be disposed of properly per the regulations of your area.

## 17 FCC Regulatory Statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**Important:** Changes or modifications to this product not authorized by Carrot Sense could void the electromagnetic compatibility (EMC) and wireless compliance and negate your authority to operate the product.

P/N LB-20000 Rev. 2