



Patient Guide
Biosense Device and App



The Biosense Device

The Biosense® device measures breath acetone or BrAce, which is produced as a byproduct of fatty acid oxidation and the resulting formation of energy-yielding ketone bodies. Ketones are produced during times of glucose insufficiency and are released into the blood to be taken up by tissues to be metabolized for energy. The concentration of acetone in the breath indicates your level of ketone production resulting from fatty acid oxidation. The device represents breath acetone in scaled units called ACEs, from 0-40. The higher your ACEs, the more ketones are being produced. Ketosis is the term used to describe a state in which there is an accumulation of ketones in the body tissues and fluids.



Three types of Ketone Bodies and Why it Matters

There are three different ketone bodies: Acetoacetate (AcAc), Beta-hydroxybutyrate (BhB) and Acetone (BrAce). Ketones represent a third class of energy substrates for your metabolism. Under conditions of insufficient glucose, your liver converts fats into the ketones AcAc and BhB for energy. BrAce is a direct by-product of AcAc and a volatile organic compound measurable in the breath. AcAc and BhB both circulate in the blood and can interconvert within cells. Urinary dipsticks measure AcAc as unused AcAc is excreted in the urine. Urine tests provide a range of ketone levels rather than a discrete value. Further, AcAc levels in the urine decline after several weeks of keto-adaptation limiting their utility to track nutritional ketosis over time. BhB measured in venous blood provide the highest level of accuracy but must be done in a lab. At-home BhB finger prick tests measure BhB in capillary blood but are inconvenient and costly over time.

Why Measure Multiple Times Daily

As ketone levels often vary greatly throughout the day, a single ketone measurement provides a limited view of an individual's metabolic state. To capture cumulative progress over time, our clinical study calculated a daily area under the curve (AUC.) The AUC is a summary of the accumulated depth and duration of nutritional ketosis each day. It answers the question, "how deeply and for how long have I been in ketosis?" with a single number. Our clinical data showed a very high correlation between breath and blood AUCs ($R^2 = 0.83$) when both measurements were taken 3 times daily. Stated differently, using a breath or a blood device to take multiple measurements per day captures the high variability of daily ketone levels and provides very similar indications of overall ketone activity.

What Breath Acetone Measurements Tell You About Your Health

Measuring breath acetone allows you to track if you are producing ketones and indicates your level of fatty acid oxidation. Ketosis may result in many health benefits for you such as, fat loss, glucose control, blood pressure regulation, improved cognitive function, and has been studied for its role in increasing longevity. Ketosis is influenced primarily by diet and fasting. Exercise, stress (increasing cortisol and insulin), and sleep have also been shown to impact levels of ketosis. As diet plays a primary role in fatty acid oxidation and ketone formation, it is important for you to follow a dietary plan resulting in lowering glucose and increasing ketones. Research has shown a variety of dietary plans to be effective, including carbohydrate restriction, calorie-restriction, and more. Though following a plan may be easy for some patients, people often react very differently to the same lifestyle change, making it challenging to identify which food choices and in which quantities affect each patient's ketone production rate. Therefore, measuring matters. When you track ketones, it allows your practitioner to be better informed about how you react to interventions in not only diet, but also exercise, stress and sleep.



Downloading the app

Click one of the links below to download the Biosense app to your mobile device, or search Biosense in the app store.



Pairing device to phone

Turn on the Biosense device and enable Bluetooth on your phone. Open the Biosense app and turn on your Biosense by pressing the check button for three seconds.

If the device is not on this screen, the device can still be paired as long as it is not asleep. Select "Pair a Device", then select your device from the device list. Your device name will appear as "B" or "BiosenseXXXX"(example: Biosense1234). If you have successfully paired, you will see a message that says Device Connected. After the Biosense device and app are manually paired for the first time, they will automatically connect each time the app is open and the Biosense device is on and nearby.



Using the device



Biosense has a simple two-button interface and an onboard LED screen that guides the user through the measurement process. To begin taking a measurement, the first thing you need to do is power on your device. To do so, press and hold the check button until you see the blue Biosense logo.

Once the device is on, it will immediately enter into a preparation stage as indicated by the Preparing Device screen, vibrating as it warms up and calibrates. This process can take up to 120 seconds to warm up. After device preparation is complete, you will see a new screen that says Press Start. At this point, you can press the check button to take a measurement. You will then be prompted to blow into the device.



The optimal blow technique consists of a normal inhale and then a full exhale with medium force (think blowing up a balloon or blowing a bubble). The device waits until the end of the exhalation to begin measuring. Keep breathing until you hear two short vibrations from the device. Finally, after a brief analysis period (around 15 seconds), the measurement result is displayed on the device screen. The result is also placed on a color scale that indicates where your fat burn rate lies on the overall spectrum of ketosis.

Device settings



History: View the previous 10 measurements or delete measurements stored on the device. Biosense can store a maximum of 100 measurements.

Set Time: Manually set the device clock. If you pair to the app, the app will automatically set the device clock and manual time setting is not necessary.

Info: View device information like serial number, firmware version, sensor status and microphone status. If the sensor status shows CLEAN, run a clean cycle. If the mic status shows FAIL, contact support@mybiosense.com.

Clean: Run an extended clean cycle. A red dot next to the settings gear indicates a sensor clean is recommended.

Home: Navigate back to the device Home Screen.

Charging your device

Charge your Biosense device using the provided Micro USB charging cable and an approved LPS power supply (maximum rating 5V/1A). Your device needs two hours for a full charge. When your device is charging, the LED underneath the mouthpiece will glow red. The red LED light will automatically shut off once the device has reached a full charge.

Cleaning your device

Clean your Biosense device once a week. Remove the mouthpiece from the device before cleaning by gently squeezing its base and pulling it away from the device. Use a cloth and water to clean your mouthpiece. Do not use cleaning wipes that contain alcohol and do not clean the white filter on the device.

Syncing readings to the app

When your Biosense device and phone are properly paired, there are two ways to sync measurements to the app. Keep your Biosense app open to automatically sync your results during a measurement. To maintain accurate breath ketone readings, ACEs should be measured several times a day.

Pairing Icon

The pairing icon on the top right corner of the home screen indicates whether you are connected (blue) or not connected to Biosense (gray). You can tap on your pairing icon to connect Biosense if it does not connect automatically.



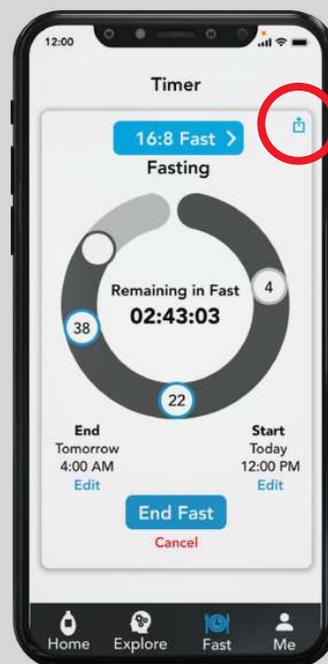
NOT connected to Biosense



CONNECTED to Biosense

Share results

You have the option to share your results with your practitioner by clicking the share button in the upper right corner of the app. Sharing results and being honest about your experience is an integral component of the Biosense program. It allows both you and your provider to measure success against daily habits.



Using the Biosense App

The Biosense app is designed to provide you with biomarker feedback and insights on a daily basis.

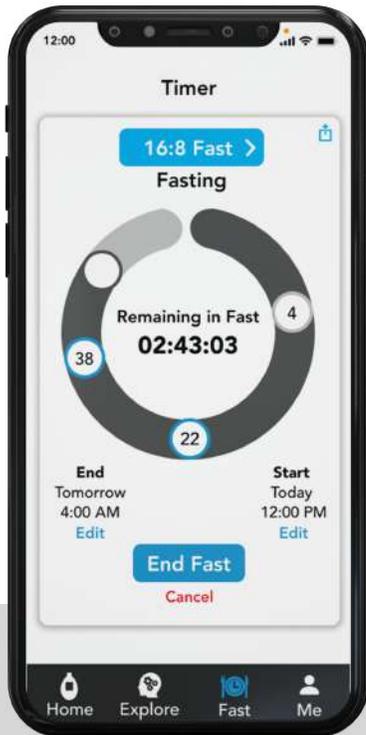
The **Ketone Dose** answers, “how long and deeply you have been in ketosis,” estimated from your ACEs measurements. The Average **Ketone Dose** (week, month, and year time frames) only takes into account the days when you measured with Biosense.



The **ACEs** popup tells you your most recent **ACEs** measurement, your level of ketosis, and associated potential health benefits.

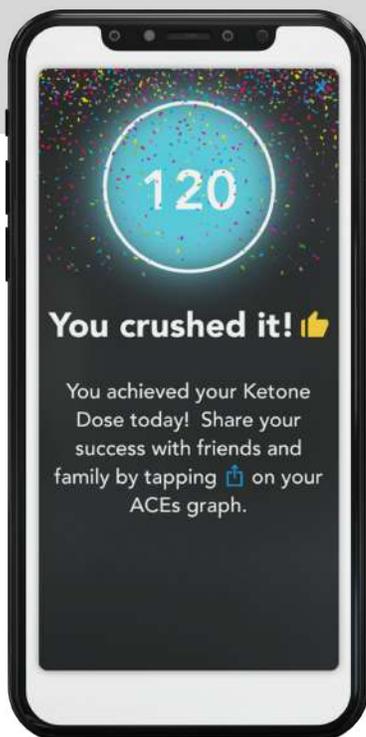


Real-time biofeedback so you understand how diet, exercise, and fasting impacts fat burn levels.



You can monitor your body's increasing fat burn levels to **optimize their fast.**

Easy to access reports that help you track their progress and help you guide treatment decisions.



Positive reinforcement to keep you motivated to get into and stay in a fat burn state.



Questions & Answers

Q/A 1 USING YOUR BIOSENSE BREATH KETONE METER

How do I use the Biosense device?

Biosense is simple and easy to use. Follow this quick start guide to get familiar with the Biosense device.

Biosense has a simple two-button interface and an onboard LED screen that guides you through the measurement process. To begin taking a measurement, the first thing you need to do is power on your device. To do so, press and hold the check button until you see the blue Biosense logo.

Once the device is on, it will immediately enter into a preparation stage as indicated by the Preparing Device screen, vibrating as it warms up and calibrates. This process can take up to 120 seconds.

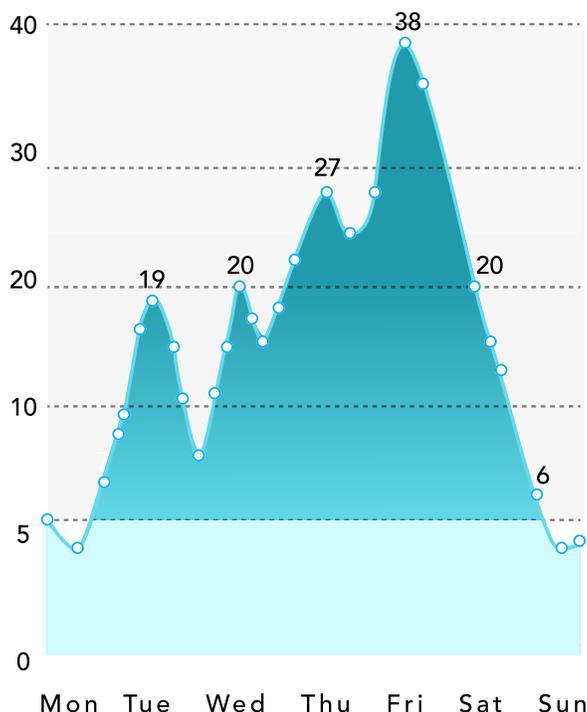
After device preparation is complete, you will see a new screen that says Press Start. At this point, you can press the check button to take a measurement. You will then be prompted to blow into the device.



Q/A 2 TARGET ACES: DIFFERENT DEPENDING ON YOUR GOALS

What should my target ACEs be?

Biosense readings are reported in units called ACEs, a unique unit of breath acetone ranging from 0 (no ketones) to 40 (high ketones). When referring to target ACEs, there is no one-size-fits-all answer because the target ACEs vary depending on your goals.



However, with readings that go up to 40, this scale needs to be further expanded upon. While a ketone reading of >5 is the standard goal for weight loss patients, even higher ketone levels play an essential role in tapping into the benefits of ketosis beyond weight loss.

Understanding the ACEs unit

Biosense ketone measure results are reported in units called ACEs. Tap on the below arrows to better understand potential health benefits associated with specific ACE ranges.

1-4 ACEs

Low Ketones

-  Still burning glucose as primary fuel.
-  Burning fat for fuel.
Lowering blood sugar.
Decreasing belly fat.
Reducing blood pressure.
Improving lipid profiles.
-  Increasing mental clarity.
Easing inflammation.
Enhancing brain health.
-  Regenerating cells.
Enhancing health and energy.

5+ ACEs

Weight Loss

-  Still burning glucose as primary fuel.
-  Burning fat for fuel.
Lowering blood sugar.
Decreasing belly fat.
Reducing blood pressure.
Improving lipid profiles.
-  Increasing mental clarity.
Easing inflammation.
Enhancing brain health.
-  Regenerating cells.
Enhancing health and energy.

10+ACEs

Cognitive & Anti-Inflammatory

-  Still burning glucose as primary fuel.
-  Burning fat for fuel.
Lowering blood sugar.
Decreasing belly fat.
Reducing blood pressure.
Improving lipid profiles.
-  Increasing mental clarity.
Easing inflammation.
Enhancing brain health.
-  Regenerating cells.
Enhancing health and energy.

15+ ACEs

Healthspan & Autophagy

-  Still burning glucose as primary fuel.
-  Burning fat for fuel.
Lowering blood sugar.
Decreasing belly fat.
Reducing blood pressure.
Improving lipid profiles.
-  Increasing mental clarity.
Easing inflammation.
Enhancing brain health.
-  Regenerating cells.
Enhancing health and energy.

ACE Measurement Frequency

To maintain accurate breath ketone readings, you should measure your ACEs at least **three times a day**.

Breath and blood ketones both vary dramatically over the course of a day. The patterns of ketone level changes are dependent upon the specific day and the individual, what they eat, how they exercise, etc. Although breath and blood ketones tend to rise and fall together, there is often a time offset between changes in blood ketones and changes in breath ketones. Speak with your Practitioner for more information regarding offset times.

Benefits of frequent testing for users

Monitoring your ketones provides you real-time feedback about how your dietary and lifestyle choices affect your ketones. The Biosense breath ketone meter provides a much tighter feedback loop than the weight scale, which is the traditional feedback tool for obesity management and lifestyle change programs. With Biosense, you can get feedback about the effect of a particular choice on their fat burn rate in as little as one hour. This creates a strong psychological connection between the actions you are taking and the results you observe, a connection that strengthens as feedback frequency increases. As you learn more about your body and the effects of your choices, you will become increasingly invested in your own success.



Q/A 4 THE CONNECTION BETWEEN ACE READINGS AND WEIGHT LOSS

How do ACE readings relate to weight loss?

When you are beginning a new health plan targeting ketosis, it is essential to consider the following general guidelines for interpreting your results. It is not uncommon to remain in the 0-3 range for the first few days while glycogen stores are depleted.

0-2 ACEs – not in ketosis. ACEs readings of 0-2 represent the background fat burning rate present in all individuals regardless of diet or lifestyle. Even individuals who are eating a high-calorie or high carbohydrate diet can have an ACEs reading of 2.

3 ACEs – slightly elevated ketones. An ACEs reading of 3 is the lowest reading that can be associated with elevated ketones.

4-5 ACEs – transitioning into ketosis. Ketones are elevated, and your patients/clients are transitioning into a primarily fat-burning state. This is the point at which glycogen stores are being depleted in the liver.

>5 ACEs – definitively in ketosis. ACEs readings above 5 represent an even deeper state of fat burn. Some individuals, particularly those with diabetes and metabolic disease, may not be able to achieve ACEs levels above 4-5. For this reason, a patient with a maximum ketone level of 4-5 ACEs should be considered successful.



Q/A 5 GLYCOGEN: ESSENTIAL TO UNDERSTANDING A LOW KETONE READING

What do consistently low ketone readings indicate?

While it is quite common for those already practicing low-carb eating and/or practicing fasting to achieve ketone levels in the 10-40 ACEs range, patients new to these dietary changes will often begin with ketone levels less than 5 ACEs. Low ketone readings are not only normal when first beginning your Biosense journey, they are to be expected.

Glucose is the first metabolite the body will use to convert to energy via the TCA cycle to produce ATP. Once glucose is utilized, the liver will metabolize its stored glycogen to convert to energy. Once the liver's glycogen stores are depleted, the body will begin to convert stored triglycerides into free fatty acids (FFA) and oxidize the FFA's to enter into the TCA cycle to produce ATP. Ketone bodies are formed as a byproduct of FFA oxidation.

Basically, the body needs to burn through all glycogen stores before it begins to burn fat as energy, causing ketone levels to rise. This process can take up to a few days.

It is important to note that consistency is key to remaining in ketosis. For example, when an individual eats a high calorie or high-carbohydrate meal, their glycogen fills back up. If they were to then resume their diet after the high calorie meal, they will have to first burn through their newly stored glycogen before they will start to see their ketones rise. This interplay between glycogen and fat metabolism is the single most important concept to consider when interpreting ketone data. It is not uncommon to remain in the 0-3 range for the first few days while your glycogen stores are depleted.



Q/A 6 FACTORS THAT AFFECT KETONE LEVELS

Factors that affect an ACEs measurement

Factors that affect ketone levels include, but are not limited to:

1. Calorie intake:

- ACE levels increase with fasting and caloric restriction
- Conversely, ACEs drop, often suddenly, after an excessively high calorie meal

2. Carbohydrate intake

- ACEs increase as dietary carbohydrates are reduced
- Conversely, ACEs drop, often suddenly, after an excessively high carbohydrate meal

3. Exercise duration and intensity

- During exercise, the body first will deplete stored glucose in the blood for energy, and then utilize stored glycogen in the liver. Once glucose and glycogen stores are depleted, the body uses ketones for energy.
- The short-term effect of exercise on ACE levels depends on whether ketones are elevated or not before exercise. If ketones are elevated before exercise, they often drop temporarily after exercise before rising again (this is due to the use of ketones during exercise and a

temporary spike in blood glucose caused by cortisol, which is released during exercise). If ketones are low before exercise, they tend to simply rise after exercise, without experiencing a drop.

Take ACE measurements about an hour post-exercise to allow time for the ketones to rise again after a temporary drop.

4. Stress levels

- High stress levels increase cortisol production raising glucose production in the liver and lowering ketone levels.
 - Stress can be indirectly affected through factors like sleep. Speak to your patients about good sleep hygiene and stress management techniques as they directly and indirectly affect fat oxidation and ketone production.

5. Alcohol

- Consuming alcohol will affect ACE levels. It is recommended that you wait at least 5-6 hours or wait until the next day post-consumption to measure ACEs.