

Biosense™ Device



Intended Use

The Biosense system is intended for single-user testing of breath acetone. The device is not intended for diabetes management. It is indicated for home (lay user) or professional use in the management of individuals seeking to reach or maintain physiologic ketosis as it relates to maintaining a healthy lifestyle.

The system should not be used to diagnose or treat any disease or condition. Follow your healthcare professional's advice before making any changes to your disease management or lifestyle program.

Device Repair and Disposal

For warranty and repair information, visit mybiosense.com.



This device contains a lithium-ion battery that must be disposed of separately from other household items.

Device Operational Environment

Tested for:



Indoor use



Altitudes of less than <math><2000\text{m}</math>



Ambient temperature: 50°F – 95°F
(10°C – 35°C)



Relative humidity: 15% - 80%

Device Transportation Environment



Ambient temperature: 32°F – 140°F
(0°C – 60°C)



Relative humidity: 15% - 80%



Atmospheric pressure: 700 - 1250 HPA

Frequently Asked Questions: mybiosense.com/faq

Questions? Email us at
support@mybiosense.com



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Breath Ketone Monitor



Device Settings

Pressing the  button takes you to the Settings menu. Press  to scroll through the following options and press  to select.

History: View the previous 10 measurements or delete measurements stored on the device. Biosense can store a maximum of 50 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 including serial number, firmware version, sensor status and microphone status.

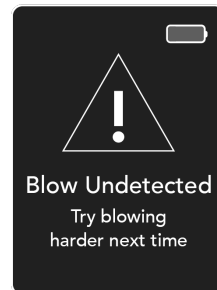
Clean: A red dot next to Clean in the device Settings indicates that a sensor clean is recommended. With the device plugged in, use this feature to run an extended sensor cleaning process.

Home: Navigate back to the device Home screen.

Errors

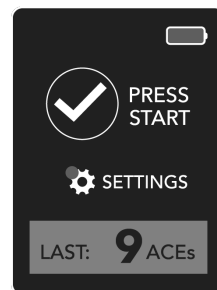
Blow Undetected

An overly gentle blow may not be detected. Make sure you are blowing with medium strength. Continue blowing until you feel two short vibrations, which signals that a breath sample has been obtained.



Exposure to Solvents

Biosense contains a highly sensitive chemical sensor. Solvents like hand sanitizer, cleaning products, and other aromatics may interact with the sensor and interfere with device preparation and clearing. If the sensor is effected by environmental solvent exposure or is otherwise unable to adequately prepare, a red dot will appear on the screen and direct you to run a sensor Clean (see Device Settings).




Charging Your Device

Charge your Biosense device using the provided Micro USB charging cable and an approved AC power adapter (maximum rating 5V/1A). Your device needs 3 hours to fully charge. When your device is charging, the LED underneath the mouthpiece will glow red. Once fully charged, the LED will turn off.



Cleaning Your Mouthpiece

It is recommended to clean your Biosense mouthpiece once per week. Before cleaning, remove the mouthpiece from the device 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.

Sleep Mode

After completing a measurement, the device will go to sleep. To manually put the device to sleep, hold down the  button for 2-3 seconds and release. The device battery will slowly discharge while sleeping. If you know you will not measure for several days, plug in your device or power off completely.

Powering Off/On

To fully power off the device hold the  button down for about 12 seconds and release until the logo disappears. To power on the device, hold the  button for 2-3 seconds and release.

Factory Calibration and Quality Control

Each Biosense device undergoes an individual factory calibration process to ensure precise measurement performance.

Accuracy and Precision Testing

The Biosense device represents breath acetone in scaled units called ACEs.

Precision testing was performed with NIST-certified gas standards and results were analyzed for accuracy and repeatability (10 devices, 225 measurements). The graph below shows how Biosense accurately measures lab gas standards with very high repeatability.

