

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 <2000m
-  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

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Questions? Email us at support@mybiosense.com




Frequently Asked Questions: mybiosense.com/faq



Breath Ketone Monitoring System



Device Settings

Pressing the  button takes you to the SETTINGS menu. Once inside 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 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 from the SETTINGS menu. If the mic status shows FAIL, contact customer support.

Clean: run an extensive sensor cleaning process. A red dot next to Clean in the device SETTINGS indicates that a sensor clean is recommended.

Home: navigate back to the device Home screen.

Errors

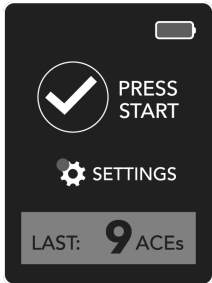
Blowing too gently

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



Exposure to solvents

BIOSENSE contains a highly sensitive chemical sensor. Solvents like hand sanitizer, nail polish remover, and other aromatics may react with the sensor and interfere with sensor preparation and clearing. If the sensor is affected by environmental solvent exposure or is otherwise unable to adequately prepare, a red indicator will appear on the screen and direct you to run a sensor Clean (see Device Settings).





Smart Clean

If your device determines that extra sensor warmup or clearing is necessary, it will automatically activate the Smart Clean process. Periodic Smart Clean activations are a normal part of regular device use and do not indicate device malfunction.

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 2 hours for a full charge. When your device is charging, the LED underneath the mouthpiece will glow red.

Sleep, Power Off & Hard Reset

After completing the measurement, the device will go to sleep. To manually put the device to sleep, hold down the  button for 2-3 seconds and release. To fully power off the device or to initiate a hard reset, hold the  button down for about 12 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.

Tips For Success

For best results, wait 60 minutes after:

- Eating
- Smoking/vaping
- Drinking sodas or flavored waters
- Consuming items with flavorings such as:

- Toothpaste
- Mouthwash
- Cough drops
- Breath mints Chewing gum
- Lip balm
- Artificial sweeteners

Do not test after consuming alcohol. For best results wait until the next morning.

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.**

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.

