



# INSTRUCTION MANUAL

Welcome to LEVL! We are excited to ignite your wellness journey.

The LEVL is designed to detect trace amounts of acetone in your breath when your body is burning fat. Simply breathe into the LEVL device and your breath is captured and analyzed by our groundbreaking nanosensor, providing you with an instant measurement of your body's acetone concentration in Parts Per Million (PPM). Previous clinical research demonstrates a correlation between the amount of acetone detected in the breath and body fat burned, giving you a reliable indicator of fat loss. **A breath measurement of 2 PPM or greater indicates an elevated state of fat metabolism that should correspond to a loss of at least 1/2 lb. of body fat per week.**

The LEVL device is designed to provide insight into the effectiveness of your food and exercise choices by allowing you to monitor your fat burning state through the measurement of breath acetone. To achieve the best results and consistent data points, it is important to take a measurement at the same time every day.

When the body burns fat for energy, ketone bodies are also produced. The ketone bodies are acetoacetate,  $\beta$ -hydroxybutyrate and acetone. Because fat metabolism is always taking place, every person has a degree, large or small, of ketone bodies circulating within their blood. An elevation in ketosis (i.e. ketone bodies) corresponds to an elevation in fat metabolism. When your body doesn't have enough carbohydrates to burn for energy production, it burns fat instead, which causes elevated ketosis.

Typically, the body uses glucose to meet its metabolic energy requirements. If needed, the body can shift from using glucose to using fat. Many different scenarios can cause this shift. Exercise can deplete accessible carbohydrate stores causing the body to use fats for energy production. Dietary changes that cause fat intake to increase and carbohydrate intake to decrease will alter metabolism to efficiently utilize the change in nutrients. In all of these scenarios, the body is unable to use carbohydrates for energy and, thus, shifts to using fats.

Acetone is one of the ketone bodies. Because of its small size, acetone can diffuse into the lung air and appear in breath. These trace levels of acetone in breath can be measured. In healthy individuals, changes in breath acetone correspond to changes in fat metabolism.

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## INDICATION FOR USE

The LEVL breath acetone measurement device is intended for regular measurement and monitoring of breath acetone for adults.

The LEVL device has been carefully developed for accurate, safe and fast acetone measurements from exhaled breath. However, as with any breath measurement device, proper technique is critical to obtaining accurate results. **Therefore, read the instructions carefully and thoroughly before operating.**

## OPTIMAL ENVIRONMENTAL OPERATING CONDITIONS

At the heart of the LEVL device is a state of the art nanosensor that responds to trace levels of acetone in your breath. **Due to the sensitivity of the sensor, the LEVL device should be placed in a stable environment and kept away from certain chemicals found in a clinical setting, like rubbing alcohol, cleaning products, hand sanitizers, sani-cloth wipes, air fresheners, essential oils and other strong fragrances.**

Do not expose the LEVL device to temperatures below -4°F, temperatures above 140°F, or relative humidity above 90%. Prolonged exposure (>3 months) to temperatures above 113°F may cause permanent damage to the device. The device may be exposed to direct or filtered sunlight.

Handle with care. Keep dry. If the LEVL device gets wet, it may stop operating properly or stop operating completely.

Keep the LEVL device clear of lint and dust as these may interfere with breath measurements. This includes pet fur or dander and pests.

To avoid inaccurate measurements, calibrate the LEVL device before initial use, after sensor module replacement and when prompted by the device.

The user is required to periodically calibrate the device, change the sensor and change the filter.

Users with the following known contraindications, should not use the LEVL device:

- Unable to participate in light exercise (e.g., walking)
- Severe lung disease which would prevent them from providing a breath sample through a large bore tube (i.e., drinking straw)

Use of the LEVL device is not intended as a substitute for consultation with your physician.

Make sure all cords are out of arms reach of children.

This device is not designed for use by children. Use by children may result in injury to the child or damage to the LEVL device.

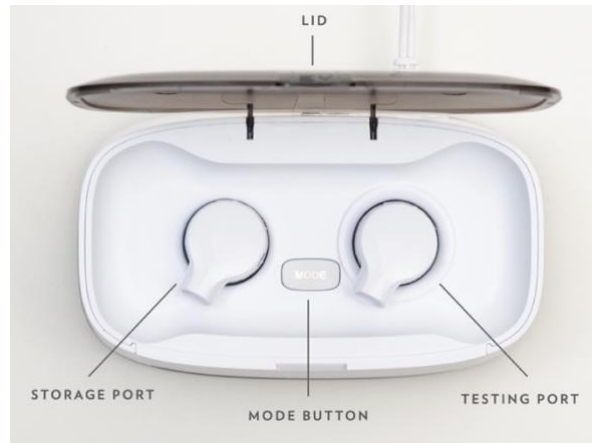
Do not modify this equipment without authorization of the manufacturer. Modification of this equipment voids the warranty. Only the sensor is user serviceable. All other parts of the device are not designed to be accessed by the customer.

Do not operate the LEVL device at altitudes above 6,500 feet

**WARNING!** Mains power is applied to the LEVL device when it is plugged into the wall, even if no lights are illuminated. Unplug the LEVL device to disconnect mains power before replacing the sensor.

Do not expose the internal battery to heat or fire.

Batteries must be disposed of properly. Do not open or shred batteries. Consult local recycling rules before disposal.

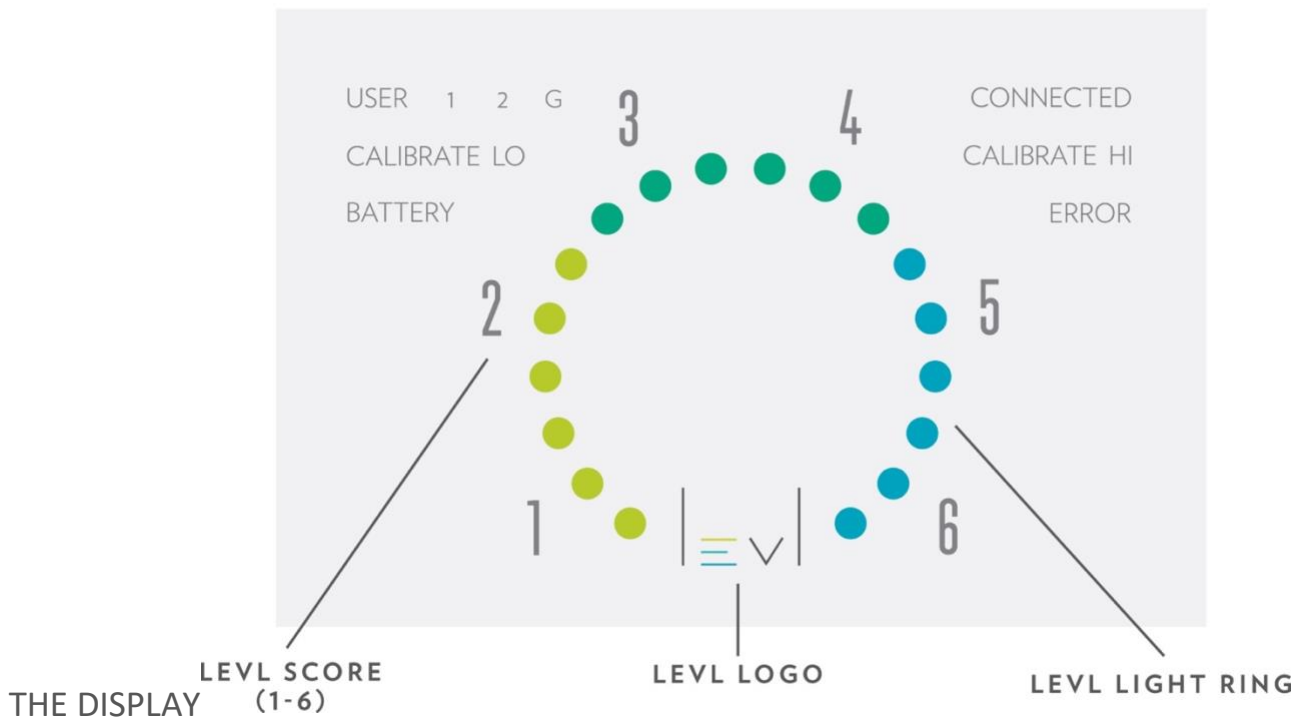


**WARNING!** CHOKING HAZARD - Small parts. Not for use by children.

## THE LEVL DEVICE COMPONENTS

- LID – Protects the breath pods; closing the lid during the breath sampling process will initiate the breath analysis
- TESTING PORT – Receptacle contains tubing that allows breath from the breath pod to be pulled across the sensor for analysis
- STORAGE PORT – Receptacle allows storage of inactive breath pod
- MODE BUTTON – Toggles between USER 1, USER 2 and GUEST user
- DISPLAY – Communicates LEVL score and status of Bluetooth connection, calibration, active user and battery.
- BREATH PODS – Allow for exhaled breath to be captured in preparation for the LEVL device analysis.





- USER INDICATOR – Select user (via mode button) to ensure measured breath acetone is properly recorded.
- CONNECTED – Verifies that the device is paired to a mobile device via Bluetooth
- CALIBRATE LO – Illuminates during the LO calibration process
- CALIBRATE HI – Illuminates during the HI calibration process
- BATTERY – Indicates the device is not connected to wall outlet power
- ERROR – An error has occurred. Please refer the Error and Troubleshooting Table on Page 14.
- LEVEL LIGHT RING – The rotating ring indicates a measurement is in progress
- LEVEL SCORE DISPLAY – Indicates your LEVL score. See the mobile app for in-depth results.
- LEVEL LOGO – Indicates power; a blinking LEVL logo indicates the device is preparing for a new measurement

## ACCESSORIES

- Breath Pods (2)
- HI & LO Calibration Canisters
- AC Power Cord
- Disposable Mouthpieces – Qty of 25 (Optional for use)

## LEVEL SENSOR TECHNOLOGY

The LEVEL device is capable of measuring acetone directly from the users' breath.

Using a specially designed nanosensor, this device is able to detect the level of acetone in exhaled breath. Upon initial startup, the sensor is required to complete a 24-hour sensor conditioning procedure in order to achieve the most accurate results. It is recommended that regular calibrations are performed to maintain optimal performance.

Following these instructions will help provide accurate measurements over the life of the sensor.

## OPERATION

The operating ambient temperature range for the LEVEL device is 59-82 °F (15 to 28 °C).

## STORAGE

Do not expose the LEVEL device to temperatures below -4°F, temperatures above 140°F, or relative humidity above 90%. Prolonged exposure (>3 months) to temperatures above 113°F may cause permanent damage to the device.

Handle with care. Keep dry.

## LEVEL DEVICE MODES

Mode	Description
Stand-by with illuminated logo	The LEVEL device is powered on and ready to receive a breath sample for analysis
Stand-by with blinking logo	The LEVEL device is powered on and preparing for a measurement.
Battery Powered (Sensor Protect)	The LEVEL device is disconnected from wall power and unable to accept a breath sample for analysis. The device battery will maintain sensor performance for at least 2 hours. Please plug the unit into wall power to ensure continuous sensor performance. If LEVEL is without power for over 2 hours, please <b>complete a 24-hour sensor conditioning procedure.</b>
Off	The LEVEL device is unpowered. The next connection to wall power will require a 24-hour sensor conditioning procedure before breath measurement.

## SETUP FOR FIRST MEASUREMENT

### UNPACKING

- Remove outer package sleeve.
- Open packaging box.

- Remove the LEVL device and place on flat surface away from chemicals found in common clinical settings like rubbing alcohol, cleaning products, hand sanitizers, sani-cloth wipes, air fresheners, essential oils and other strong fragrances.
- The LEVL device should be set up in an area that has access to a standard outlet and allows the device to be easily connected/disconnected from AC power.
- Remove other LEVL device accessories from the package and confirm quantities.

## POWER UP SEQUENCE [24 HOURS]

- Plug the AC power cord into the LEVL device and place the breath pods in the storage and testing ports.
- Connect the AC power cord to a standard outlet to start the LEVL device power-up sequence. **The POWER-UP sequence takes 24 hours.**
- The LEVL logo is solidly illuminated when the backup battery is charging.
- Once the back battery is charged, the LEVL logo will blink to indicate the power-up sequence is in progress and the sensor is being prepared for use. Please do not disconnect from the wall outlet power for the next 24 hours while the sensor is being prepared.
- **Calibration lights will start blinking around 12 hours, but please allow a full 24 hours for the sensor to stabilize before performing the calibration sequence.**

**NOTE** If the ERROR light blinks, see Error and Troubleshooting Table on Page 15.

## DESKTOP SOFTWARE APP SETUP (FOR IN CLINIC TESTING)

- Your LEVL shipment will include a Bluetooth USB dongle. Insert into USB port on your computer or tablet.
- Download the LEVL Desktop App from <https://levlcare.com/software/>

## PAIRING THE DEVICE WITH THE LEVL DESKTOP SOFTWARE APP

- Open the app and follow the instructions for pairing the LEVL device to your computer.
  - Press MODE button one time to select USER 1
  - Press and hold the MODE button for about 7 seconds until CONNECTED starts to flash
  - Press CONNECT DEVICE in app to complete pairing.
- Ensure the USB port is CONNECTED with green check mark.
- Ensure the Server is CONNECTED (computer is connected to WiFi) with green check mark.
- Follow the instructions on Page 9 or in the app to perform breath test.

## MOBILE APP SETUP (FOR REMOTE PATIENT MONITORING)

- Download the LEVL app from the App or Google Play Store.
- Create a LEVL profile in the app.

## PAIRING THE DEVICE WITH THE LEVL MOBILE APP

- Log in to the LEVL app on your tablet or mobile device.
- Open the LEVL app on your mobile device and open the lid on the LEVL device.
- On the app, press the settings menu on the top right of the screen (indicated with three horizontal bars) and select LEVL DEVICE.

- Press CONTINUE TO CONNECT DEVICE
- Press the mode button one time to select USER 1 (Note: The LEVL device can be used by a guest by pressing the mode button three times until G illuminates. Guest data will not be stored in the device or sync with the LEVL app.)
- When USER 1 is illuminated, press and hold the mode button for 7 seconds to enable pairing.
- Confirm that CONNECTED is blinking on the device and press CONNECT DEVICE on mobile app to complete device pairing.
- Wait for confirmation that the device is connected. Press CONTINUE.
- The LEVL device is ready for a breath measurement when the LEVL logo is solidly illuminated.

## DEVICE CALIBRATION

For first time use, pair the LEVL device to the software application *before* calibrating. Calibrating before the pairing process will cause the LEVL device to ask for Calibration again after it is paired. Calibration lights will flash after the LEVL device's 24 hour power up process and 14 days after last calibration indicating a calibration is required. **The calibration process takes approximately 6 minutes.**

- Open the lid on the LEVL device.
- Place the following items next to your LEVL device:
  - Breath pod
  - LO calibration canister
  - HI calibration canister
- **NOTE** Either breath pod can be used for calibration, but it must be placed in the testing port (on the right side of the device) for measurement.

## CALIBRATE LO

IMPORTANT! Please read all steps below before proceeding with LO calibration.

- Open the lid.
- Press mode button 3 times to select GUEST (USER G is illuminated).
- Press and hold the mode button for approximately 7 seconds until CALIBRATE LO is illuminated.
- Locate the large opening on the base of the breath pod.
- Place the base of the breath pod over the nozzle on the CALIBRATE LO canister.

The following three steps should be performed quickly to avoid the dilution of calibration gas:

- Press the breath pod down on the canister nozzle for 7 seconds to fill the breath pod with LO calibration gas.
- Once the breath pod is filled with gas, place your thumb over the breath pod mouthpiece and immediately place the breath pod into the testing port (on the right side with the raised ring) of the LEVL device.
- Close Lid to start LO calibration.
  - The LEVL light ring will illuminate in a rotating pattern for 15 seconds to indicate the calibration is in progress.
  - The rotating pattern will stop and disappear when calibration LO has finished.
  - If ERROR blinks, see Error and Troubleshooting Table on Page 14



- Calibrate LO light will turn off. Wait until the LEVL logo stops blinking (this takes approximately 5 minutes) to move to the next step.

## CALIBRATE HI

IMPORTANT! Please read all steps below before proceeding with HI calibration.

- Open the lid.
- Press mode button 3 times to select GUEST (USER G is illuminated)
- Press and hold the mode button for approximately 7 seconds until CALIBRATE LO is illuminated.
- Press the mode button once (CALIBRATE HI is illuminated)
- Remove the breath pod from the testing port and locate the large opening on the base of the breath pod.
- Place the base of the breath pod over the nozzle on the CALIBRATE HI canister.

The following three steps should be performed quickly to avoid the dilution of calibration gas:

- Press the breath pod down on the canister nozzle for 7 seconds to fill the breath pod with HI calibration gas.
- Once the breath pod is filled with gas, place your thumb over the breath pod mouthpiece and immediately place the breath pod into the testing port (on the right side with the raised ring) of the LEVL device.
  - Close lid to start HI calibration.
  - The LEVL light ring will illuminate in a rotating pattern for 15 seconds to indicate the calibration is in progress.
  - The rotating pattern will stop and disappear when HI calibration has finished.
- When the LEVL logo is solidly illuminated, the device is in stand-by mode and is ready to perform a measurement.

Replacement calibration canisters will ship with your LEVL subscription. Contact LEVL support if you need new canisters.

**WARNING!** Calibration canisters are not designed for air transportation and are NOT permitted in carry-on bags of commercial or private aircraft.

## PREPARING FOR A BREATH MEASUREMENT

**Please wait 60 minutes before taking a LEVL measurement** if you have been exposed to the following. Rinse mouth with water for 5 seconds to remove residual chemicals from your mouth. These items may cause false high measurements and, in some cases, may cause the sensor to fail.

- Alcohol, Mouthwash, Toothpaste
- Breath mints, Chewing Gum, Cough Drops
- Tobacco or e-cigarettes
- Lip balm or Lip Stick (wipe off before test)
- Non-sugar Sweeteners (e.g., Sorbitol) and Water enhancers (e.g., Mio)

## TAKING A BREATH MEASUREMENT (DEKSTOP SOFTWARE APP FOR IN-CLINIC USE)

- Open the LEVL app and ensure the SERVER and USB device are CONNECTED with a green check mark. (Pairing instructions can be found on the page 7.)
- Enter the Patient Name, Age, Weight and Sex. Click PROCEED TO TEST.
- Open the lid on the LEVL device.

- Press the mode button 1 time to select USER 1.
- Insert a disposable straw into the mouthpiece of the breath pod.
- Take a deep breath in and hold it for 5 seconds.
- Place lips around the disposable mouthpiece to form a complete seal. Exhale for 5-10 seconds into the breath pod.
- Remove the disposable straw from the breath pod and place breath pod into testing port (on the right side) of the LEVL device.
- Close the lid to start measurement.
- The LEVL light ring will illuminate in a rotating pattern to indicate the measurement is in progress.
- The results will be displayed in approximately 15 seconds.
- The detailed results will appear in the LEVL App - acetone volume in parts per million (PPM) and fat pounds burned per week.
- The front of the LEVL device will also display a score in single digits between 1 and 6 for up to 5 minutes.
- The LEVL logo will blink while the device prepares for a new measurement – 3 minutes.
- The LEVL device is ready to perform a measurement with the logo is solidly illuminated.

#### TAKING A BREATH MEASUREMENT (MOBILE APP)

- Open the LEVL app and ensure it is CONNECTED to the LEVL device. (Pairing instructions can be found on the page 7.)
- Open the lid on the LEVL device.
- Press the mode button 1 time to select USER 1.
- When USER 1 is illuminated, remove the breath pod from the LEVL device and hold in hand. If using a disposable mouthpiece, insert into the mouthpiece of the breath pod.
- Take a larger than normal breath and hold it for at least 5 seconds.
- Place lips around the breath pod or the disposable mouthpiece to form a complete seal. Exhale for 5-10 seconds into the breath pod.
- Place breath pod into testing port (on the right side with the raised ring) of the LEVL device. If using the disposable mouthpiece, remove it from the breath pod before placing in the testing port.
- Close the lid to start measurement.
- The LEVL light ring will illuminate in a rotating pattern to indicate the measurement is in progress.
- The results will be displayed in approximately 15 seconds.
- Once the measurement is complete, the LEVL light ring will display a LEVL score between 1 and 6 for up to 5 minutes.
- Visit the LEVL app for an in-depth look at the results including acetone parts per million (PPM), fat pounds burned per day and fat kcals burned per day.
- The LEVL logo will blink while the device prepares for a new measurement – 3 minutes.
- The LEVL device is ready to perform a measurement with the logo is solidly illuminated.

## CLEANING YOUR LEVL DEVICE

**WARNING! Failure to follow the proper cleaning protocol may cause inaccurate measurements, the sensor to burn out, or damage to the internal components of the LEVL device.**

The following **non-alcohol**, cleaning wipe is the only product that has been approved to de-sanitize the LEVL device. This bleach-based wipe is on the EPA list for fighting the coronavirus.

### [Clorox Healthcare Bleach Germicidal Disinfectant Wipes](#)

## CLEANING PROTOCOL

### LEVL device exterior

- Wipe down the top of the lid, sides, front and back of the LEVL device.

### Under the lid

- Wipe down the underside of the lid.
- Wipe storage port and the testing port.
- Wipe all other areas under the lid.
- Allow five minutes to dry before using the LEVL device.

### Breath Pods

- Pull apart the breath pod base and cap. Wipe the inside and outside of each part.
- Allow the breath pod parts to air dry for at least five minutes.
- Reassemble the breath pod and store in a sanitary place until its next use.

## SENSOR MODULE REPLACEMENT

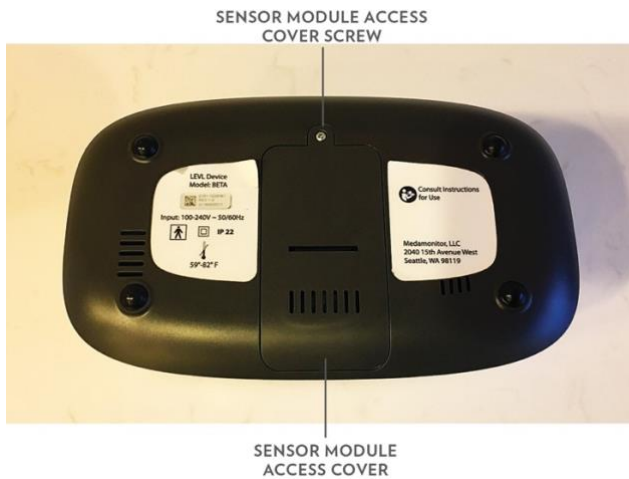
- **IMPORTANT! Please read all steps below before proceeding with the sensor module replacement. You must power OFF the LEVL device completely before changing out the sensor.**
- The LEVL sensor should be replaced once a month. Replacement sensors are available for purchase on [LEVLnow.com](#).
- REQUIRED EQUIPMENT:
  - Replacement LEVL Sensor Module
  - 1/8" Phillips head screwdriver
  - Provided 5/64" Allen wrench (included)



## POWERING DOWN THE DEVICE

- Open the lid
- Press the mode button 3 times to select GUEST mode.
- Verify the USER and G light are both illuminated
- Press and hold the mode button for about 7 seconds until the CALIBRATE LO light is solidly illuminated.
- Press the mode button once so the CALIBRATE HI light is solidly illuminated.
- Press and hold the mode button for about 10 seconds until the BATTERY light starts blinking.
- Once the BATTERY light stops blinking, verify all lights are extinguished. This process takes 15 minutes.
- You can now unplug device from the outlet.

- **WARNING!** Do not proceed if the LEVL logo remains illuminated as this indicates the presence of AC power. Mains power is applied to the LEVL device when it is plugged into the wall, even if no lights are illuminated. Unplug the LEVL device to disconnect mains power before replacing the sensor.
- Remove the breath pods.
- Find the sensor module access cover on the bottom of the LEVL device.



- Loosen and remove the access cover screw with 1/8" Phillips head screwdriver.



- Loosen and remove the sensor module screws with the provided 5/64" Allen wrench.
- Pinch the sensor module finger removal tab and remove sensor module.
- Insert the new sensor module.
- Gently tighten the sensor module screws with the provided 5/64" Allen wrench.
- Replace access cover and tighten screw with the Phillips screwdriver.
- Perform the POWER UP sequence [24 hours] and calibration process (page 7).

## RESETTING THE DEVICE

- Follow the instructions above for POWERING DOWN THE LEVL DEVICE.
- Once the device is powered down and unplugged, wait 10 seconds then plug the device back into the outlet.
- Verify LEVL logo light is blinking. (This takes a few seconds)

- Wait the 24-hour conditioning period.
- Verify both the CALIBRATE LO and CALIBRATE HI are illuminated and blinking.
- Follow the calibration process on page 8.

## BATTERY BACKUP

In the event of a power outage or disconnection from the wall outlet power, the LEVL device will operate its fan from a built-in battery for about 2 hours to protect the acetone sensor.

In the event of a power outage or the device is disconnected from AC power:

- The device will terminate any measurement in progress.
- BATTERY will remain illuminated for 2 hours.
- Bluetooth, user interface, and display are disabled.
- The LEVL device fan will continue to operate. The BATTERY light will remain illuminated, but measurements cannot be taken.
- After 2 hours, if AC power is not restored, the LEVL device will power down.
- The BATTERY light will begin blinking.
- The LEVL device fan will operate for 15 minutes and then enter the LEVL device OFF mode.
- Once the power down sequence is complete, the BATTERY light will stop blinking and the LEVL device is off.

## AIR FILTER REPLACEMENT

- **IMPORTANT!** Read all steps below before proceeding with the air filter replacement.
- Instructions to order a replacement air filter can be found on the LEVL app or at [LEVLnow.com](http://LEVLnow.com).
- Required Equipment:
  - Coin
  - Replacement filter
- Use a coin to remove the filter.
- Insert new filter in the opening, use coin to tightly secure filter.
- **NOTE** The filter should be replaced annually unless damaged or in a dirty environment.

This device and its use are covered by one or more of the following pending US patent applications: 20160341716, 20160341715, 20140371619, 20140366610. Additional US and Foreign patents pending.

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## PRODUCT SPECIFICATIONS

Device temperature range: 59-82 F, 15 to 28 °C.

Accuracy of acetone measurement: +/- 1.0 ppm Arms

Display resolution: 1 ppm

Display Range: 1-6 ppm

Humidity: 15-90% non-condensing

Electrical rating: Input - 100-120V~1A 60Hz

Service life: 2 years

Ingress protection IP22

Applied parts – breath pods and disposable mouthpieces

Mass of device 1.8 lbs. 0.8 kg

Elevation for operation: Up to 2000m / 6562 ft.

This LEVL device is specified to operate at 1 atmospheric pressure (794-1060hPA)

This device contains a Li-Ion Battery; this battery is not user replaceable.

This appliance conforms to the following standards:

IEC 14971 Medical devices – Application of risk management to medical devices.

ISO 10993-1: 2009/(R)2013 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests

IEC 60601-1-11 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC. For detailed description of EMC requirements please contact Customer Service. Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

Please do not dispose of the product in the household waste at the end of its useful life. To protect the environment, dispose the device and internal Li-Ion rechargeable battery at appropriate collection sites according to national or local regulations.

FCC regulatory information

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. Changes or modifications not expressly approved by Medamonitor could void the user's authority to operate the equipment.

**WARNING** 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. 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 unplugging the equipment and moving it to another room, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the equipment.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult an experienced radio/TV technician for help.

This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits. This equipment complies with FCC RF radiation exposure limits established for an uncontrolled environment. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized.

#### MANUFACTURED BY








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## ERROR TROUBLESHOOTING

ID	Mode	Problem	Solution	If problem persists
1	Power-Up	Device doesn't turn on	Check power cord	Call customer service.
2	Power-Up	LEVL logo is illuminated, but the LEVL logo is not blinking to indicate POWER UP status.	The device is still charging the battery. Wait up to 2 hours for POWER-UP sequence to start.	Call customer service.
3	Power-Up	The device was connected to AC 120V power and will not start measurement. LEVL logo is blinking.	Device has started POWER-UP sequence and will be unable to perform a measurement until POWER-UP sequence is completed.	Call customer service.
4	Calibration	CALIBRATE LO and CALIBRATE HI are blinking.	Calibration lights will blink 14 days after last calibration indicating a calibration is required.	Call customer service.
5	Calibration	CALIBRATE LO light remains illuminated after completed calibration process.	The calibration was unsuccessful. Please repeat the calibration process.	Call customer service.
6	Calibration	CALIBRATE HI light remains illuminated after completed calibration process.	The calibration was unsuccessful. Please repeat the calibration process.	Call customer service.
7	Calibration	CALIBRATE HI or CALIBRATE LO lights remain illuminated after calibration.	Complete calibration LO and HI within 60 minutes of each other.	Call customer service.
8	Error	ERROR is illuminated and device will not start a measurement.	Device may have been contaminated by environment. (i.e., rubbing alcohol, sanitizers)	Replace sensor module.
9	Error	ERROR is illuminated and device will not start a measurement.	Breath sensor module has reached end of life.	Replace sensor module.
10	Error	ERROR illuminates during the calibration process.	Wait until the LEVL logo is solidly illuminated, press the mode button one time to clear the ERROR and repeat the calibration process.	Call customer service.



## SYMBOL GLOSSARY

Symbol	Description
	Consult instructions for use
	Shock Protection (Applied Parts Type BF)
	Class II
<b>IP 22</b>	IP22 – Ingress protection from solid matter greater than 12.5 mm in diameter and IP22 – Ingress protection from liquid falling vertically when enclosure is tipped up 15°
	Humidity exposure range
	Atmospheric pressure range
	Bluetooth enabled device
	UL Classified device MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 AMD 1 (2012), CAN/CSA C22.2 NO 60601-1(2014), IEC 60601-1-6 AMD 1 (2013), ANSI/AAMI HA60601-1-11 (2015)