



Instructions for Use



Welcome to your OMED Health Breath Analyzer. You're already a step closer to improving your gut health.

This guide helps you to setup and use your breath analyzer so you can start collecting data and get help to understand and better control your gut health symptoms.

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FCC STATEMENT

This equipment has been tested and found to comply with the limits of 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 into 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

IMPORTANT SAFETY INFORMATION

DANGER - Misuse of electrical equipment can cause electrocution, burns, fire or other hazards.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Basic safety precautions should always be taken, including all those listed below.

Close supervision is necessary when the equipment is used by, on or near children.

Lithium-ion polymer batteries are used in this equipment. If these precautions are not taken, batteries may be at risk of damaging the device, injury or other hazards.

- Read these instructions before using the equipment.
- Keep these instructions.
- Use the equipment only for the purpose described in the instructions for use.
- Do not place the equipment in liquid, or put it where it could fall into liquid.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- Do not use equipment where aerosol sprays are being used, or where oxygen is being administered.
- Do not disassemble or modify the equipment

INTENDED USE

The OMED Health Breath Analyzer device is used, together with the associated mobile device app, to measure constituents of exhaled breath as an aid in the diagnosis of sugar/nutrient malabsorption and other conditions.

1.0 Breath Analyzer



2.0 Download the App

Your breath analyzer connects to your phone and is controlled using the OMED Health App. Download the mobile app for your Apple or Android device:



Google Play



App Store

3.0 Battery Charging

Connect your breath analyzer to a USB power source using the supplied USB cable. Ensure the battery is fully charged before first use. The side indicator will illuminate green when the battery charge is complete.

Re-charge the battery when the system indicator illuminates red. Battery status notifications are also shown in the App when the device is connected.

4.0 Wireless Connections

The app requires a WiFi or cellular connection for account setup and at regular intervals to upload the data that



Once logged in to your app, a permanent WiFi or cellular connection is not necessary for breath analyzer operation. However, Bluetooth must be switched ON in your phone settings. The app will prompt you to update your phone connection settings if needed.

5.0 Breath Analyzer Setup

1

Sign up in the app to setup your account. Login.

2

Follow the in-app screen guides to familiarize yourself with features to manage your account, collect and view data.

3

Tap '+' at the bottom of the screen and select 'Breath Sample Set Up Device'.

4

Follow the in-app instructions to setup and connect your breath analyzer. Observe the status of the system and breath sample indicators in the breath analyzer.

5

Follow the in-app instructions to collect your first breath

Scan here to view our step-by-step video guidance if you'd like some extra help.



6.0 Before you Collect a Breath Sample

Your breath analyzer is a personal healthcare product. It is intended for single person use. Do not share your breath analyzer with others.

Ensure that your mouth and lips are completely clear of any food or drink before using the breath analyzer.

Do not use the breath analyzer within 30 minutes of:

■ Brushing your teeth

■ Using mouthwash

■ Smoking

■ Vaping

■ Drinking alcohol

7.0 General Operation

Breath Sampling

Your breath analyzer requires a typical warm-up period of 2 minutes before it is ready for breath sampling.

Tap '+' at the bottom of the screen and select 'Breath Sample'.

Follow the in-app instructions to collect a breath sample.

Your breath analyzer will automatically switch off when breath sampling is complete. You do not need to power it off

Scan here to view our
step-by-step video
guidance if you'd like
some extra help.



Intervals for Breath Sampling

Time intervals between breath samples are managed by the app to ensure reliable breath analyzer performance.

The minimum time interval between breath samples is 15 minutes.

Follow guidance from a healthcare professional for breath sampling and plan to collect a maximum of 10 breath samples per day during routine operation.

Status Indicators

In addition to app notifications, your breath analyzer indicates status information on its side indicator (system) and top indicator (breath sampling) when powered on as below.

Indicator	Color	Pattern	Function
Side	Red	On	Low Battery
	Green	Repeat pulse	Battery Charging
	Green	On	Battery OK
	Red	Repeat pulse	System Fault
Top	Amber	Repeat pulse	Warm-up/Cleaning
	Green	On	Start Breath Detection
	Red	Repeat pulse	Invalid Breath Sample
	Red	5 pulses	Temperature or humidity out of range

8.0 Caring for Your Breath Analyzer

Preventing Damage

Keep your breath analyzer dry. Avoid storing or using your breath analyzer for long periods close to:

-  Strong scented products, including perfumes.
-  Hair and beauty care products (e.g. lipstick and nail polish remover).
-  Personal healthcare products (e.g. deodorants, lubricants and sun creams).
-  Household cleaning products (e.g. chemicals including alcohols, or solvents in a liquid or aerosol form).
-  Smoke (e.g. from cigarettes or cooking).

Avoid handling the breath analyzer immediately after use of alcohol-based hand gels.

Cleaning

To clean the breath analyzer without causing damage:



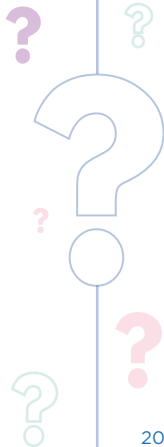
Use a soft cloth dampened with water.



DO NOT immerse in liquid, use alcohol, soap or detergent.

9.0 Troubleshooting

Scan here for further support with general operation and troubleshooting.



10.0 Technical and Regulatory Information

Product Specifications

Product Name	OMED Health Breath Analyzer
Model Number	HMBA-01
Connections	DC IN: USB C, 5.0VDC, 500mA
Operating Conditions	Temperature: 15°C - 30°C Relative Humidity: 20% - 77% (non-condensing) Maximum Altitude: 2,000m
Bluetooth Low Energy	Working Frequency Range: 2402 - 2480 MHz Maximum RF Output Power: 3.7dBm
Range	Hydrogen: 0 -100 ppm Methane: 0 - 75 ppm
Resolution	1 ppm
Hydrogen Accuracy	Mean absolute error $\leq$ 3.5 ppm (0-20 ppm range)
Methane Accuracy	Mean absolute error $\leq$ 1.75 ppm (0-20 ppm range)
Included Accessories	Instructions for Use, Charging Cable

Symbol	Meaning
	Manufacturer
	Model Type/Number
	Serial Number
	Read Instructions Before Use
	IVD Medical Equipment
	Self-test IVD Medical Equipment

Information for Users on Collection and Disposal of Old Equipment

This symbol on the product, packaging or accompanying documents means that the used electrical product should not be mixed with general household waste. For proper treatment, recovery and recycling of old products, please take them to the applicable collection points in accordance with your national legislation.



Data Protection

Your healthcare provider might ask you to only use a fictitious name, date of birth and email address when setting up your account on the OMED mobile app, in which case all information and data you provide in the course of the use of the product and app will be fully anonymized. This means we will not be able to identify you - the user.

Alternatively, if you are using your real name, date of birth and email address, any personal data provided by you and collected by the OMED mobile app will be processed in accordance with the Privacy Notice available when you download the mobile app.

Legal Manufacturer

Owlstone Medical Ltd., 183 Cambridge Science Park, Milton Road, Milton, Cambridge, CB40GJ, UK (“Owlstone”).

Your OMED Health Breath Analyzer, as received in its original packaging (“OMED Product”) is subject to a twelve (12) month warranty period by Owlstone Medical against defects in materials and workmanship when used in accordance with this guide and any other guidelines you might receive from your clinician, hospital or healthcare professional issued by Owlstone Medical (or OMED Health) from time to time (“Warranty”). If you discover a defect in materials or workmanship, you should contact your OMED Product supplier.

The Warranty shall not apply if you make further use of the OMED Product that is inconsistent with its intended purpose; or the defect arises because you failed to follow relevant instructions as to the storage, installation, commissioning, use or maintenance of the OMED Product; or you alter or repair the OMED Product; or the defect arises because of fair wear and tear, willful damage, negligence, or abnormal working conditions (including extreme temperatures).

Disclaimer

Always consult a medical professional or qualified healthcare provider to interpret the data collected by your breath analyzer and app, or if you require medical advice, diagnosis or treatment, and before undertaking a new healthcare regime. Any adaptations to current treatment should only be made if appropriate training and guidance has been provided.



Owlstone Medical Ltd declares that this wireless device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

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