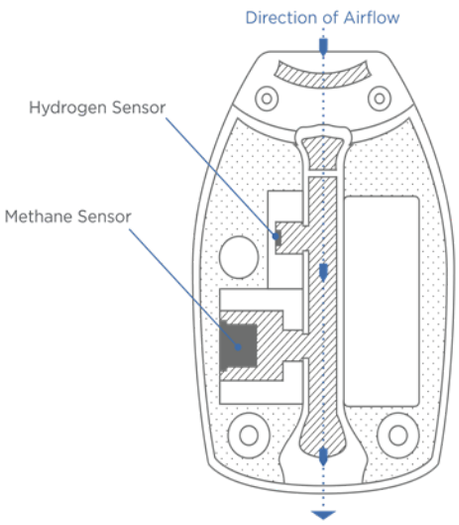
Portable At-Home Hydrogen and Methane Testing:
The OMED Health Breath Analyzer

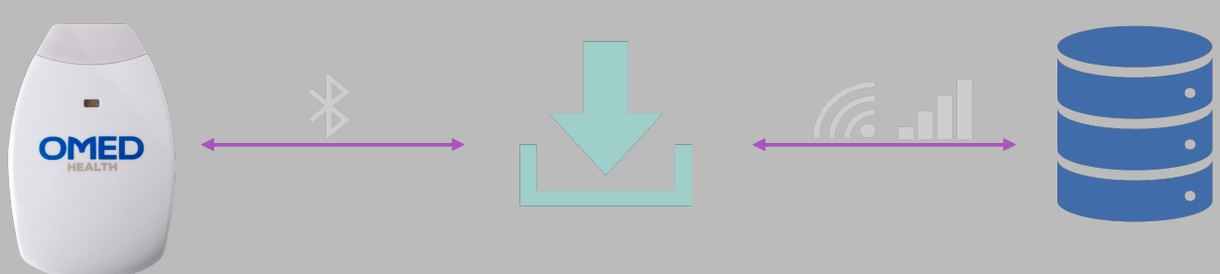


Hydrogen and methane breath tests (HMBTs) are commonly used to diagnose various digestive disorders, such as small intestinal bacterial overgrowth (SIBO) and lactose intolerance. The North American Consensus Guidelines provide a standardized process for the optimal interpretation of HMBTs and were informed by experimental work and expert opinion by a consortium of specialists.

The introduction of sensor-based devices allows for potential at-home diagnosis and longitudinal monitoring of exhaled hydrogen and methane during treatment. Longitudinal monitoring of hydrogen and methane, as opposed to a single samples, allows for clinical interpretation of treatment success. **OMED Health has developed a portable hydrogen and methane breath analyzer device for this purpose.**

The device is accompanied by a mobile app that allows Quick, convenient data collection to monitor digestive health. Users can manually log food/drink, symptoms and lifestyle records alongside hydrogen & methane levels in the breath. Progress can be tracked with daily data collection, and data can be overlaid to spot trends and correlations.

Store records automatically in a secure centralised database to share with clinicians. The device and app can be used anytime, anywhere, this can support de-centralized clinical trial designs, and provide a more convenient method through which to engage patients.



Breath Analyzer Device

- Machine learning model detects breath and predicts hydrogen/methane concentrations
- Secure bi-directional data transfer

Apple/Android App (free download)

- Create and manage User Account
- Manage and control Breath Analyzer Device
- Manually record food, drink, symptoms and lifestyle data
- Manage data and view data overlays for insights

Database hosting & infrastructure

- Secure, reliable cloud infrastructure for storage of Special Category data (UK/EU/US)
- Secure APIs for integration and interoperability with other data platforms

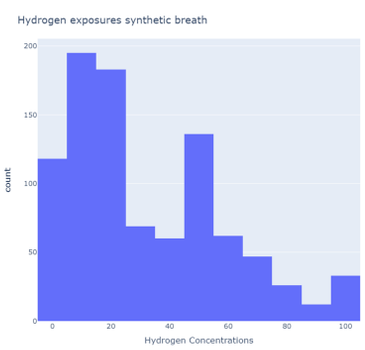
Testing the Accuracy of the OMED device

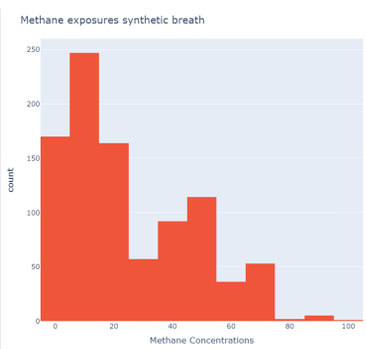
If the premise of home monitoring devices is to repeatedly use them, meaning that the probability of a false positive will increase with every subsequent test. Therefore, it is important devices used to measure the concentrations of these gases are not biased, leading to false positive diagnoses and significant impacts on patient management and well-being. For this reason, we undertook several validation studies to test the accuracy of the device.

Simulated breath:

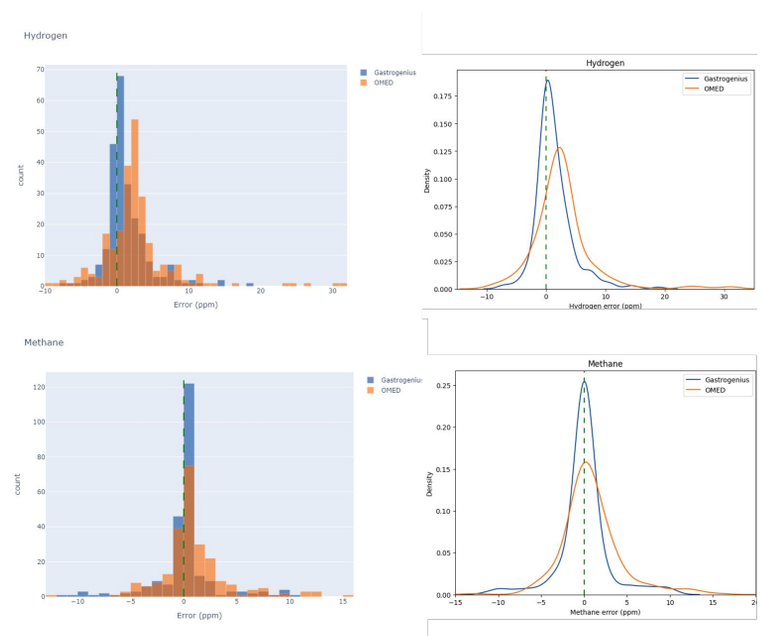
We have developed a gas concentration predictive model, simulating human breath through a rig, allowing us to measure the concentration of hydrogen and methane within a complex mix of on breath gases from multiple sensor readings across a range of temperatures and humidities.

941 synthetic breath exposures were included in a training set across a range of concentrations, temperature and humidity. This demonstrated that the OMED devices was accuracte at lower, biologically relevant concentrations (0 - ~20 ppm) for both hydrogen and methane, however the accuracy decreases above this point.





VS Gastrogenius™



To test the device using real breath, 243 breath samples were taken from 54 participants. All participants gave two breath measurements into the Gastrogenius device, a mean of the two values for hydrogen and methane were taken and assumed for this purpose to be the “ground truth” of breath concentration. Then, the participants gave a breath sample into the OMED device. The results of both were compared for both hydrogen and methane.

The results of this show very similar results between the Gastrogenius and OMED device. There was a slight tendency to underestimate hydrogen and methane concentration, and a slightly higher probability of error with the device vs the gastrogenius. Taken together, this data suggests that the OMED device is highly accurate and almost comparable to the gold-standard gastrogenius breath analyzer.

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