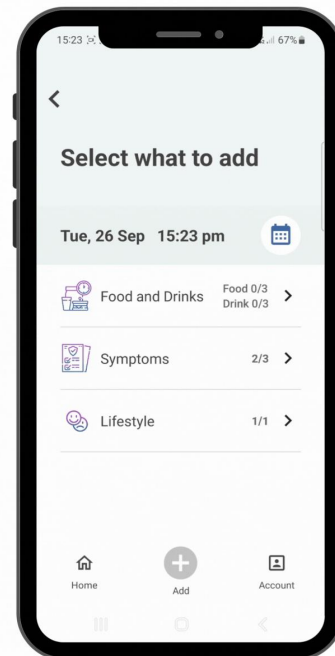


## Gut health breath tests

Portable, low cost, easy to use  
and accurate measurement of hydrogen  
and methane.

Giving healthcare professionals better  
data to support the development  
and monitoring of personalized plans.



# About Owlstone and OMED Health

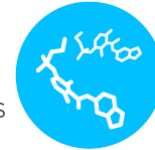
"Breath testing in every home for everyone" - Non-invasive, any time, any place diagnosis and monitoring of multiple diseases



Internal and partner-funded investment in biomarker discovery and validation with a **pipeline in cardiometabolic disease** and the **microbiome**.



**>100 PEER REVIEWED PUBLICATIONS AND SCIENTIFIC POSTERS**



**>15 YEARS' EXPERIENCE IN VOC ANALYSIS IN A RANGE OF INDUSTRIES**



Developing tests in early detection of **digestive disease, liver disease (cirrhosis and MASH), and lung cancer**.



**MULTIDISCIPLINARY TEAM -200 PEOPLE HEADQUARTERED IN CAMBRIDGE, UK**



**DEEP IP PORTFOLIO, 150+ PATENTS (GRANTED AND PENDING)**



**At-home tests and point-of-care devices** with expanding functionality made available under the **OMED Health** brand.



# Hydrogen and methane breath tests (HMBT) SIBO and carbohydrate malabsorption

## Chronic digestive health symptoms

Digestive health issues are one of the most common causes of **Work absenteeism**



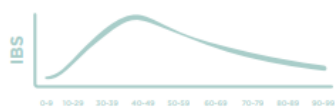
IBS is twice as common in women as in men



As many as **1 in 8 people** have gut health symptoms at any one time

Approximately **20 to 40%** of all visits to gastroenterologists are due to chronic digestive health symptoms.

People younger than age 50 are more likely to develop IBS



These stats are all estimates

It can take on average **6.5 years** to get a diagnosis through the NHS



**6 in 10** sufferers have never sought professional help



Small Intestinal Bacterial Overgrowth



Symptoms are very similar to IBS and can cause confusion during diagnosis and treatment - in fact, **up to 80% of those with IBS may also have SIBO**

SIBO is caused by an abnormal increase in bacteria in the small intestine, particularly those normally found in the large intestine.



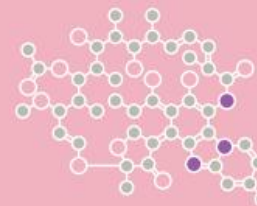
COMMON SYMPTOMS INCLUDE

- ✓ Constipation
- ✓ Diarrhoea
- ✓ Bloating
- ✓ Increased flatulence

Breath testing is a common tool to gain insights into the levels of bacteria in the intestine



Thought to affect up to **one in seven of us**



**Rifaximin** is the most common treatment for SIBO

These stats are all estimates

## Rosacea



Rosacea is an inflammatory skin condition that causes redness and a rash on the face

Many people with rosacea also experience digestive issues like bloating and stomach pain

Small intestinal bacterial overgrowth (SIBO) is caused by an **abnormal increase in bacteria in the small intestine...**



Studies have found that **SIBO is more common in people with rosacea** than healthy controls

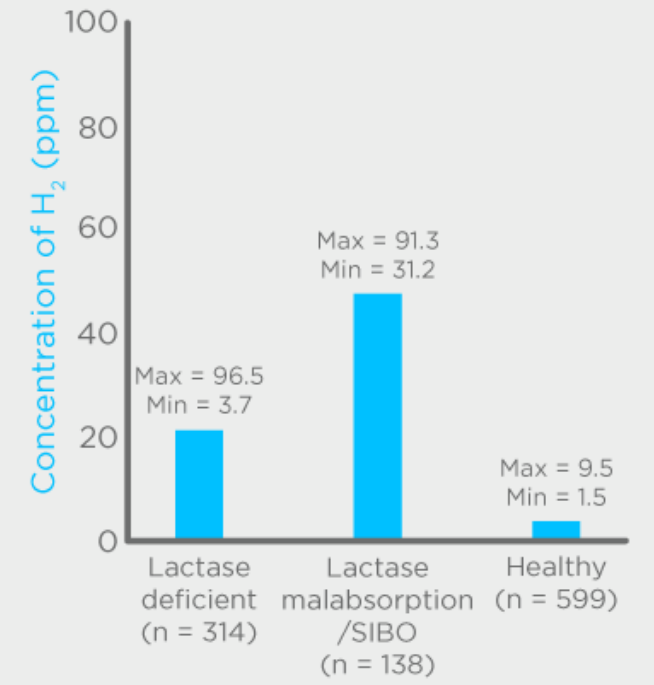
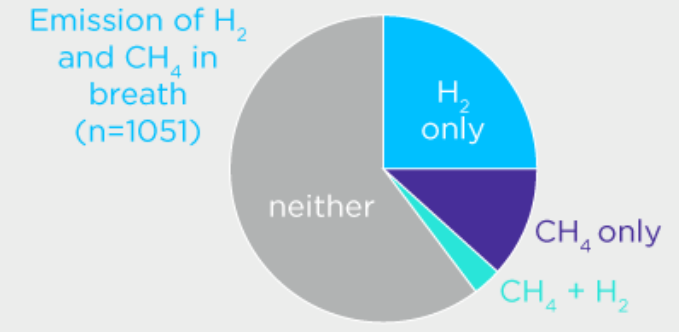
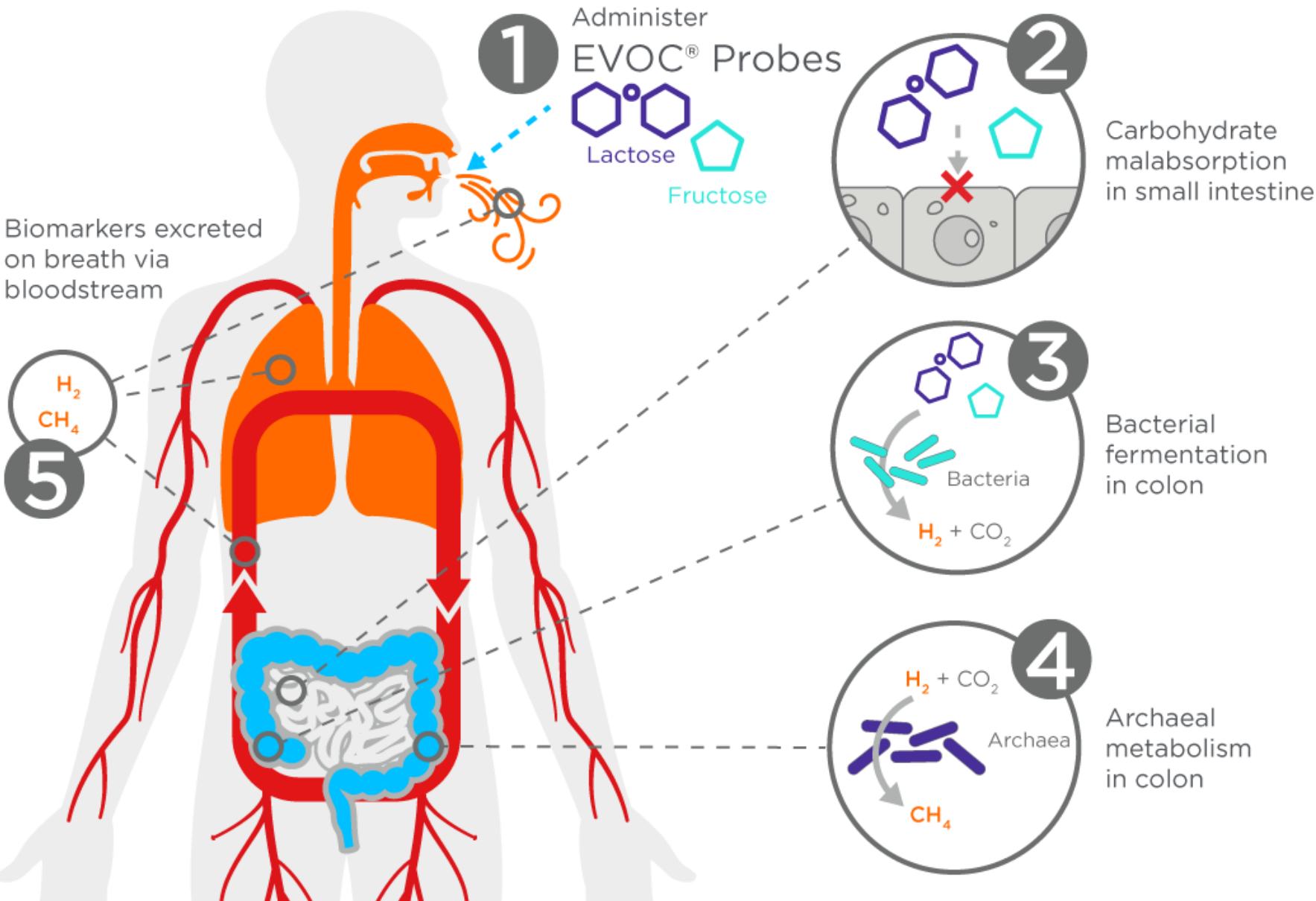
Treating SIBO can **improve skin symptoms** associated with rosacea

SIBO may cause **increased gut permeability**, allowing **inflammatory compounds** to circulate throughout the body, and **trigger skin inflammation** in people prone to rosacea



These stats are all estimates

# Biological basis for HMBT



Lactose Breath Test Results (n = 1051)  
 Houben et al. (2015) *Nutrients*

## US Consensus (2017)

### Interpretation of breath testing results

1. We suggest that a rise of  $\geq 20$  p.p.m. from baseline in hydrogen during the test should be considered positive for fructose and lactose breath testing.
2. We suggest that until better data are available, for clinical and research purposes, a rise of  $\geq 20$  p.p.m. from baseline in hydrogen by 90 min should be considered a positive test for SIBO.
3. We suggest that two peaks on breath test are not required for the diagnosis of SIBO.
4. Until further data is available, we suggest that a level of  $\geq 10$  p.p.m. be considered positive for methane on a breath test.

<http://dx.doi.org/10.1038/ajg.2017.46>

## UK Consensus (2019)

- A methane level  $\geq 10$ ppm at baseline or at any point during the test should be considered positive for methanogenesis...
- Methane levels are often  $>10$ ppm at baseline despite adherence to the pre-study diet...
- A rise above the baseline hydrogen or methane level of  $\geq 20$ ppm of hydrogen or methane at any time during the assessment is considered positive for carbohydrate malabsorption in the absence of SIBO...

[AGIP statement on HMBT use](#)

# Our experience with HMBT Kits in the UK market

~115,000 Breath Samples Analyzed



- Providing [at home breath tests](#) in the UK. Simple reliable breath tests and access to qualified GI Physiologists through our partnership with the [Functional Gut Clinic](#).
- Kits manufactured in OMED and shipped to [15 NHS hospitals](#) and [Private](#) clinics with ~115,000 breath samples measured



HOW IT WORKS ▾ WAITLIST INSIGHTS HUB ABOUT US ▾ Q

CONTACT US

## INTRODUCTION

### TAKE SOME OF THE GUESSWORK OUT OF YOUR GUT HEALTH DIAGNOSES

As a professional working in nutrition and healthcare, you'll be well aware of the worldwide healthcare burden caused by the increasing prevalence of digestive illnesses such as irritable bowel syndrome or small intestinal bacterial overgrowth (SIBO). This burden, for both patients and professionals, is exacerbated by the difficulty in obtaining a reliable, accurate diagnosis that leads to an appropriate treatment pathway.

Breath testing is a simple, non-invasive way to investigate gastrointestinal health.

Through our partnership with gut health specialists at [Functional Gut Clinic](#), we can offer your patients hydrogen and methane breath testing that can accurately confirm or eliminate the possibility of SIBO or carbohydrate malabsorption. Functional Gut Clinic experts provide a full report of results after the completion and analysis of the test.

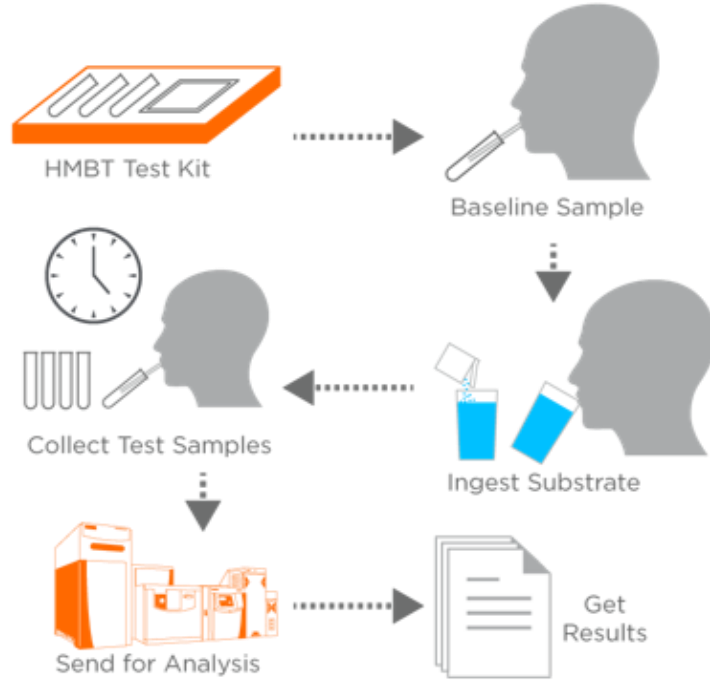
Costs for our hydrogen and methane breath testing kits are well within the applicable NHS Payment Scheme tariff. Once the kit arrives back at our lab, results will typically be available to you in 2-3 working days.



NHS tariff for performing breath testing is £356 (RN28Z UK tariff code), and the fees charged for HMBT to private customers are in the £220-£230 range

# Hydrogen and Methane Breath Test (HMBT) – How does it work?

HMBT Kit assembled at Owlstone



Breath samples analyzed in the laboratory



# The OMED Health Breath Analyzer At-Home Monitoring for Digestive Health



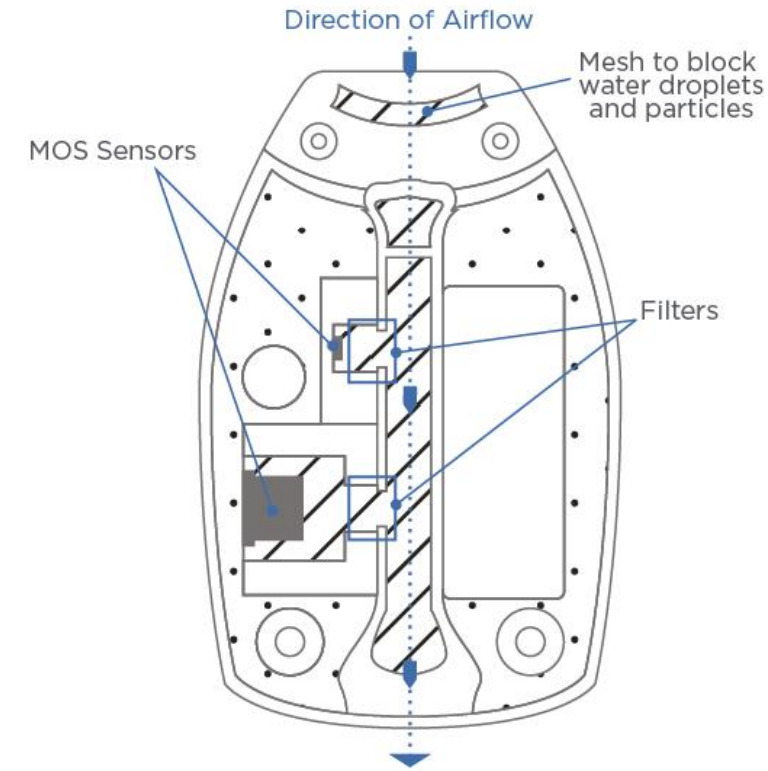
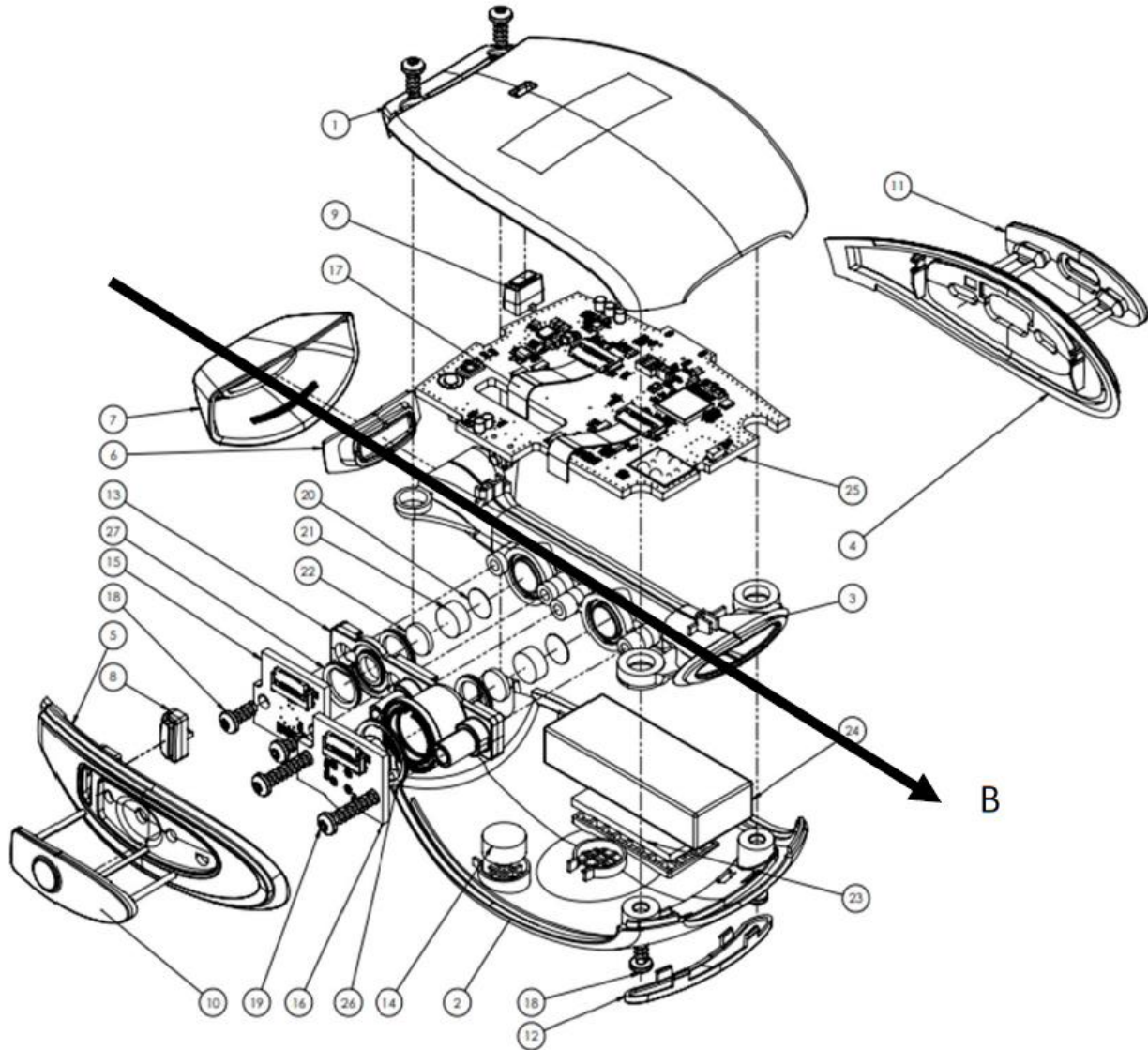
- Low-cost, real-time analysis of hydrogen & methane
- Testing multiple substrates and longitudinal treatment monitoring
- Quick, convenient data collection - log food/drink, symptoms and lifestyle records
- Track progress with daily data collection
- View data overlays to spot trends and correlations
- Store records automatically in a secure centralised database to share with clinicians





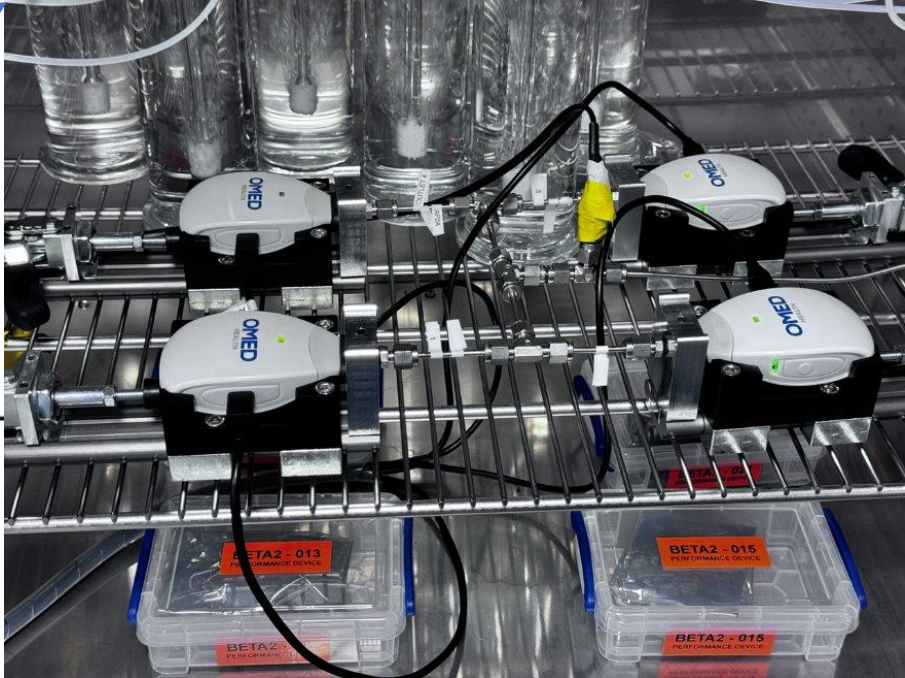
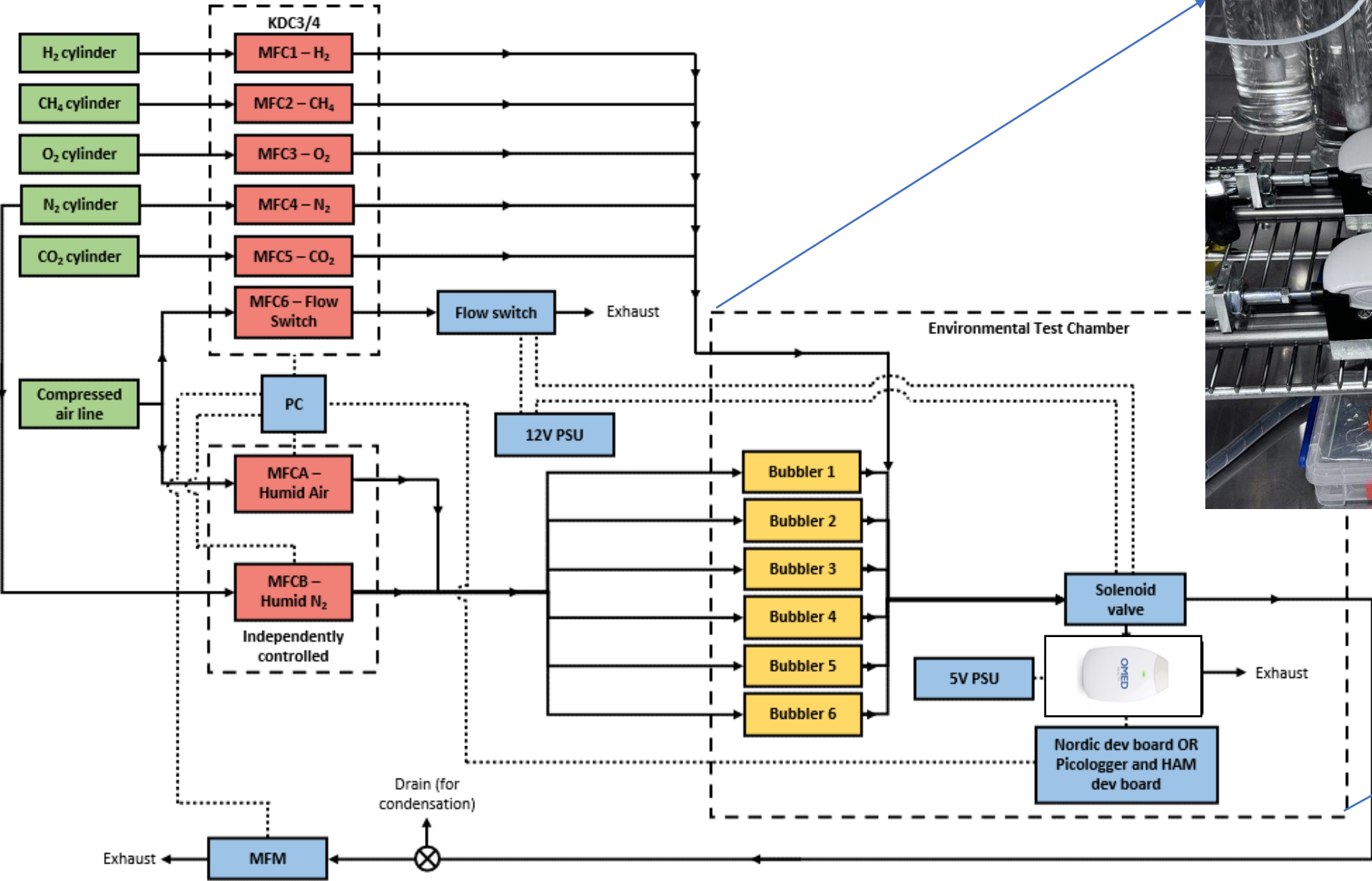
# Optimizing accuracy at the hardware system level

Selective detection in high humidity, high abundance VOC interferant background



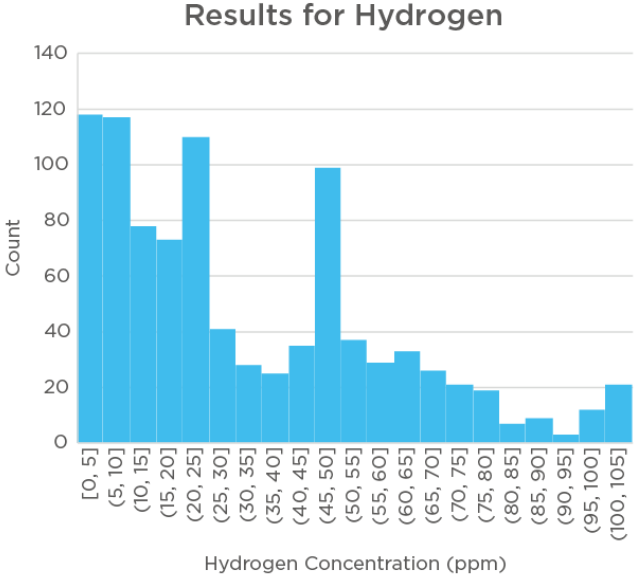
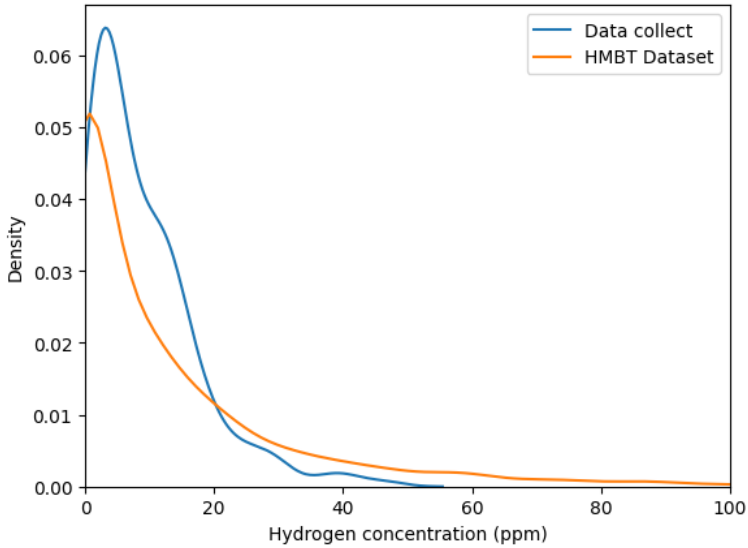
# Optimizing accuracy with AI/ML approaches

## Synthetic breath rig to train OMED model

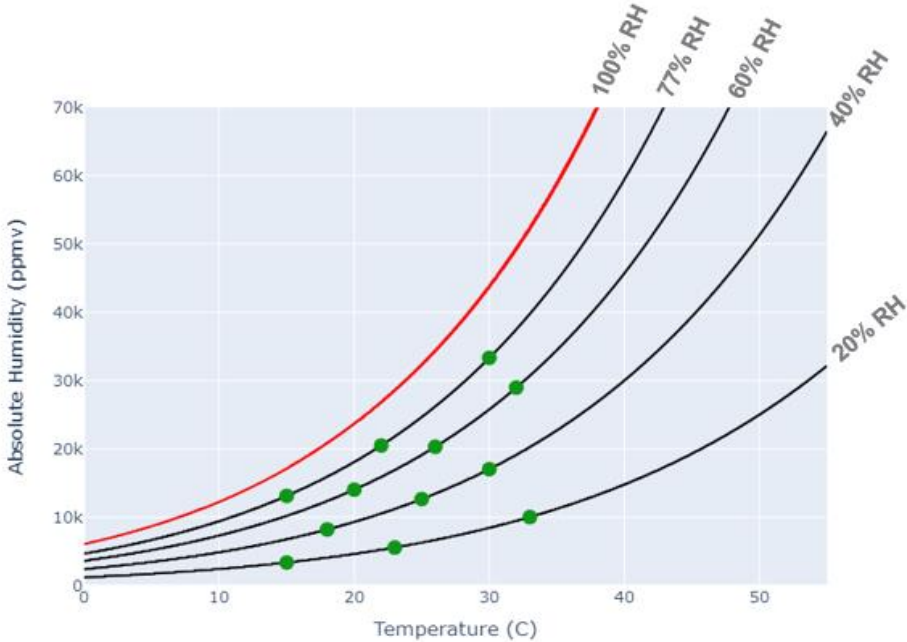
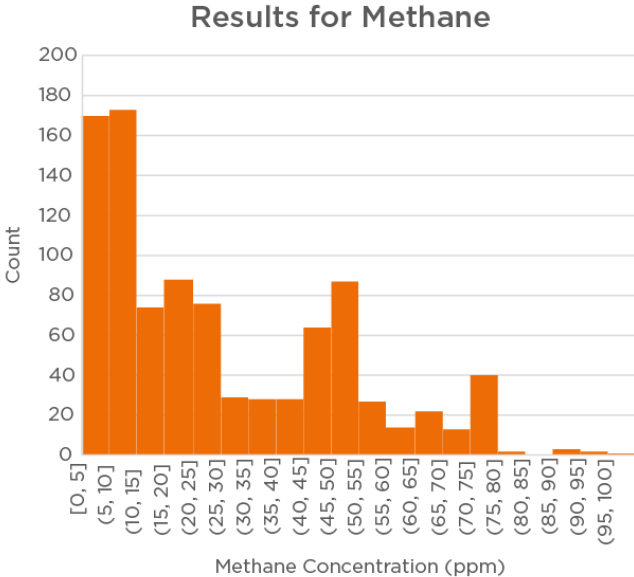
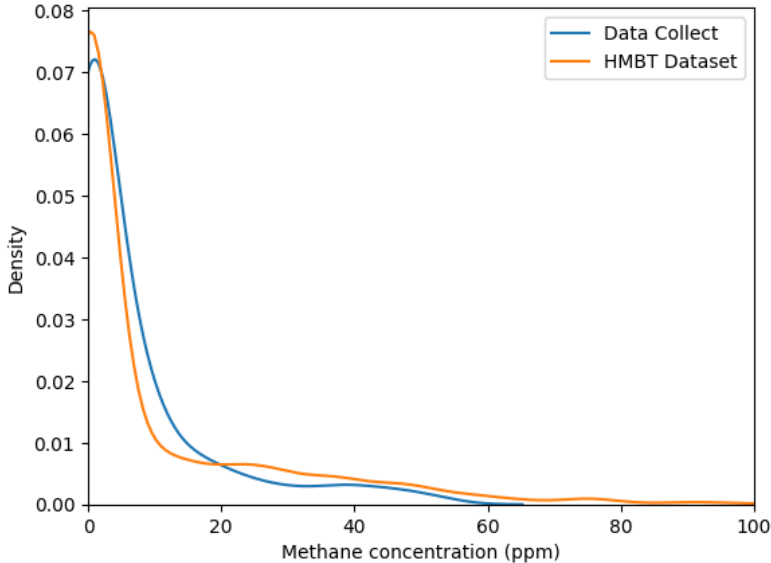


- Key:
- Pneumatic connection: —>
  - Electrical connection: .....>
  - System boundary: - - -
  - Sensor box: [Orange box]
  - Electronic component: [Blue box]
  - MFC: [Red box]
  - Gas supply: [Green box]
  - Bubbler: [Yellow box]
  - 3 way toggle valve: ⊗

# Synthetic breath rig concentrations closely match distribution of observed concentrations from clinical breath samples



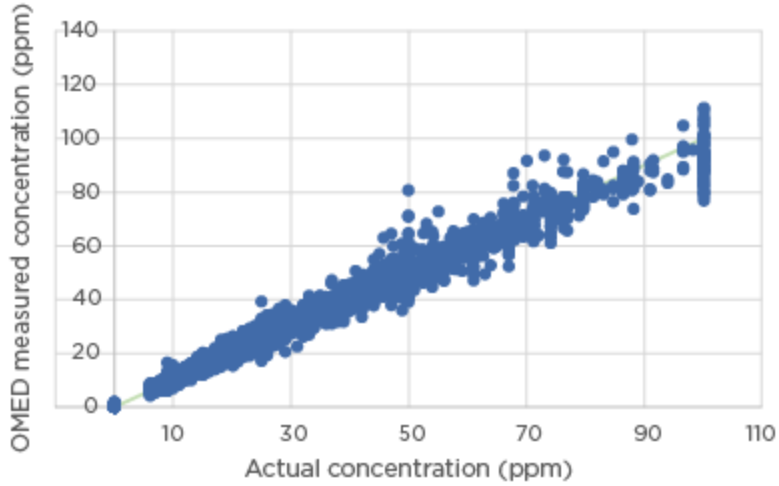
**941** synthetic breath exposures included in model training, validation and test set across a range of concentrations, temperature and humidity



# Accurate measurement of hydrogen and methane

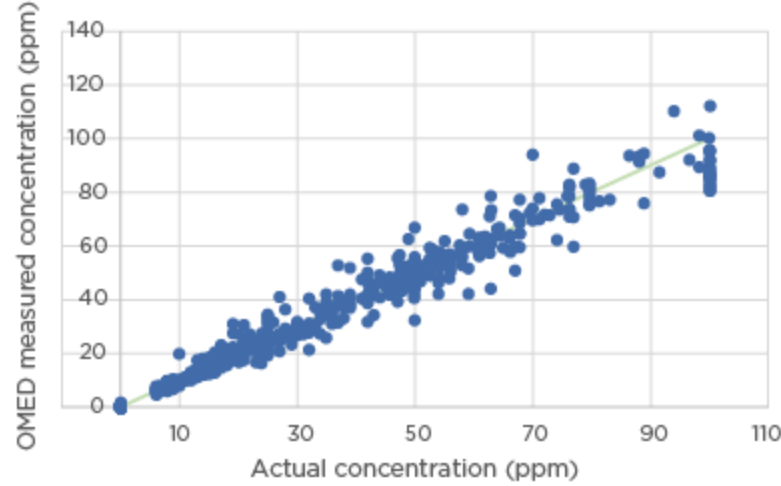
**A**

Hydrogen Training Set



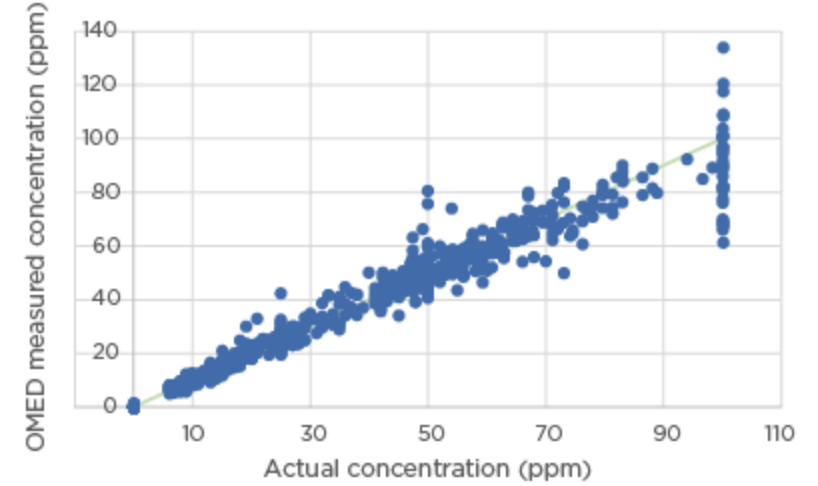
**B**

Hydrogen Validation Set

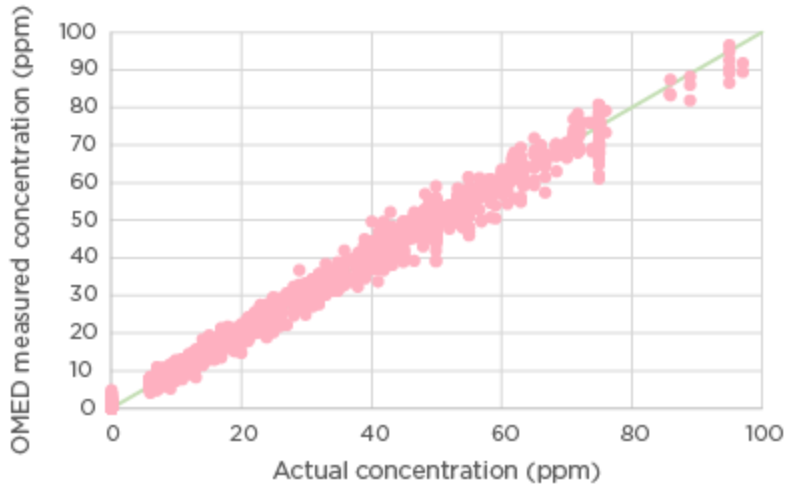


**C**

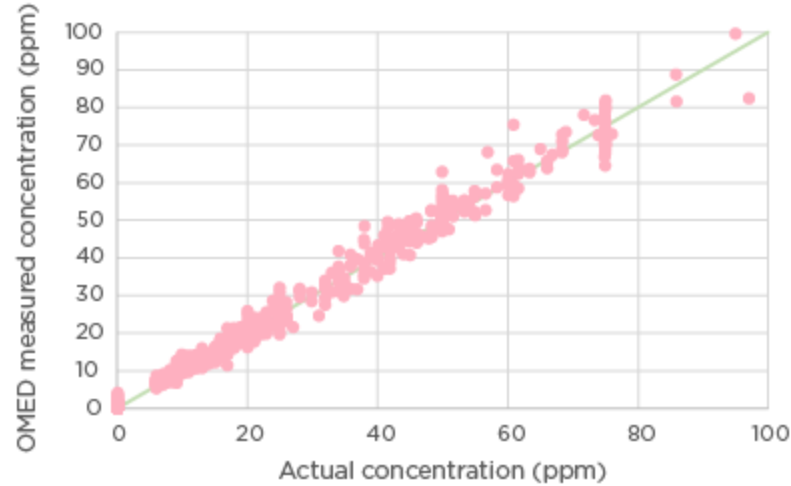
Hydrogen Test Set



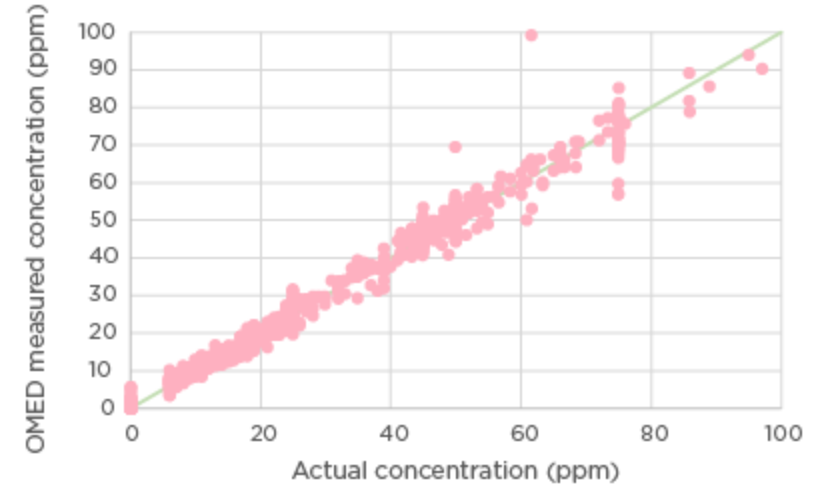
Methane Training Set



Methane Validation Set



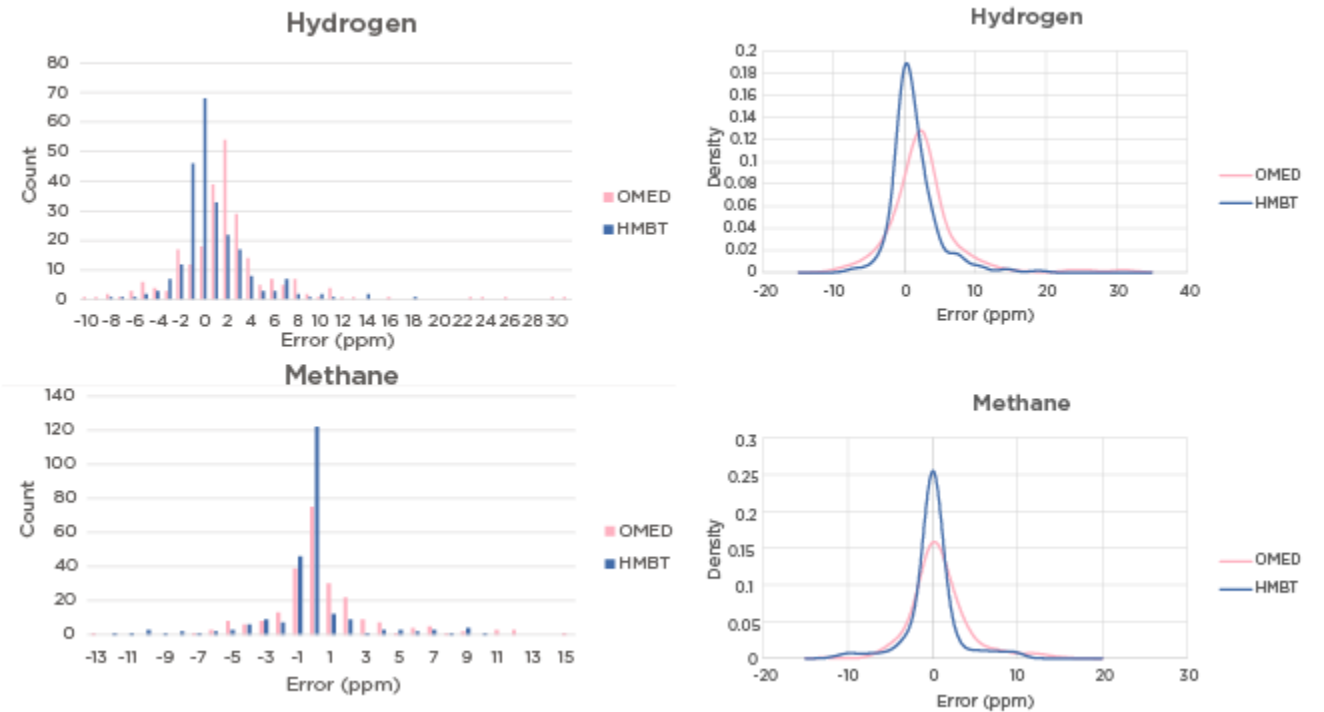
Methane Test Set



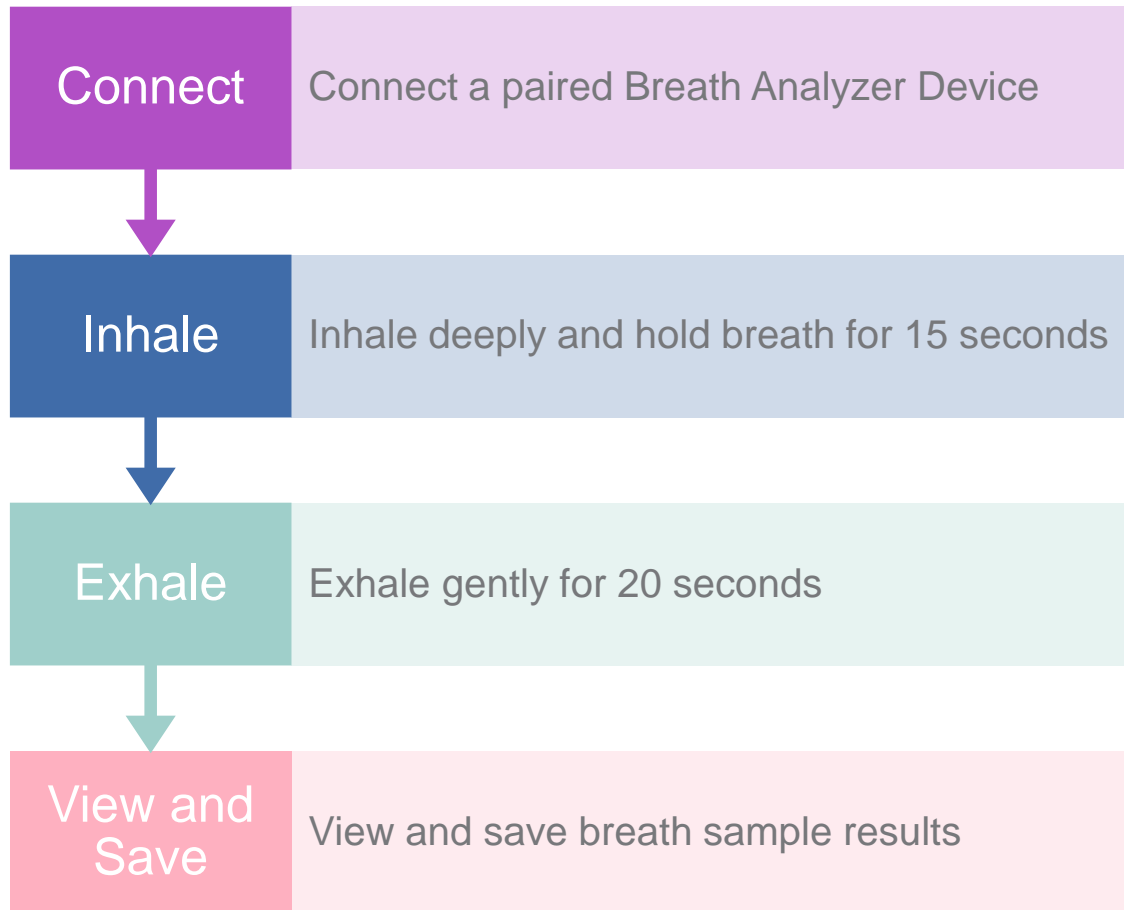
# Evaluation on real breath samples and comparison against in-clinic instruments

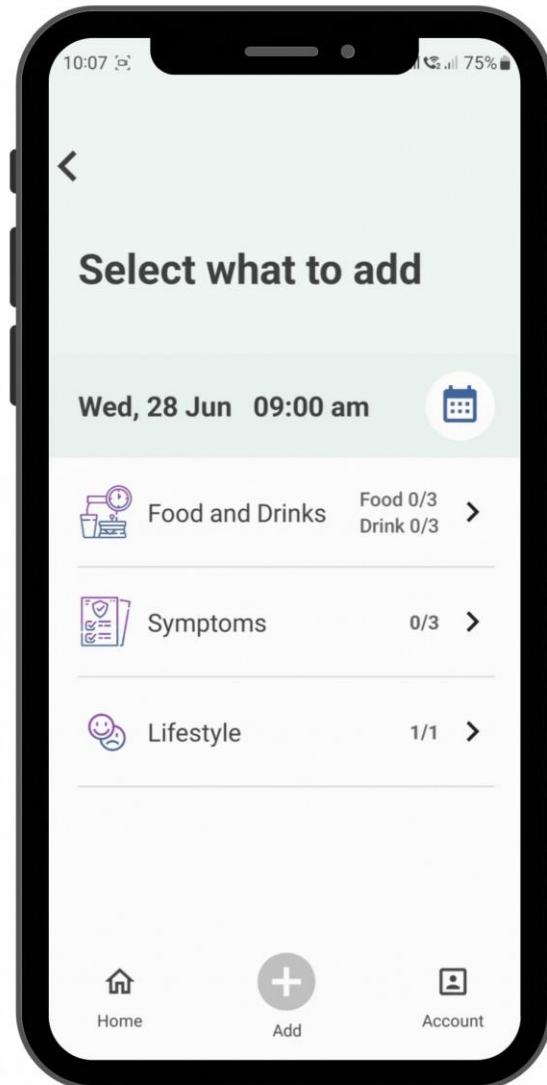


**B**



# Collect & Analyze Breath (< 3 minutes per sample)





Record food and drink details quickly and easily

- Select from your 'Favourite' list  
OR
- Add entries with keypad and 'Add to Favourite' for next time



Set the date/time as required for your entry

- Default is current date/time  
OR
- Enter time retrospectively over last 14 days

# Record Symptoms and Severity



Use Likert Scale slider bars to record key symptoms



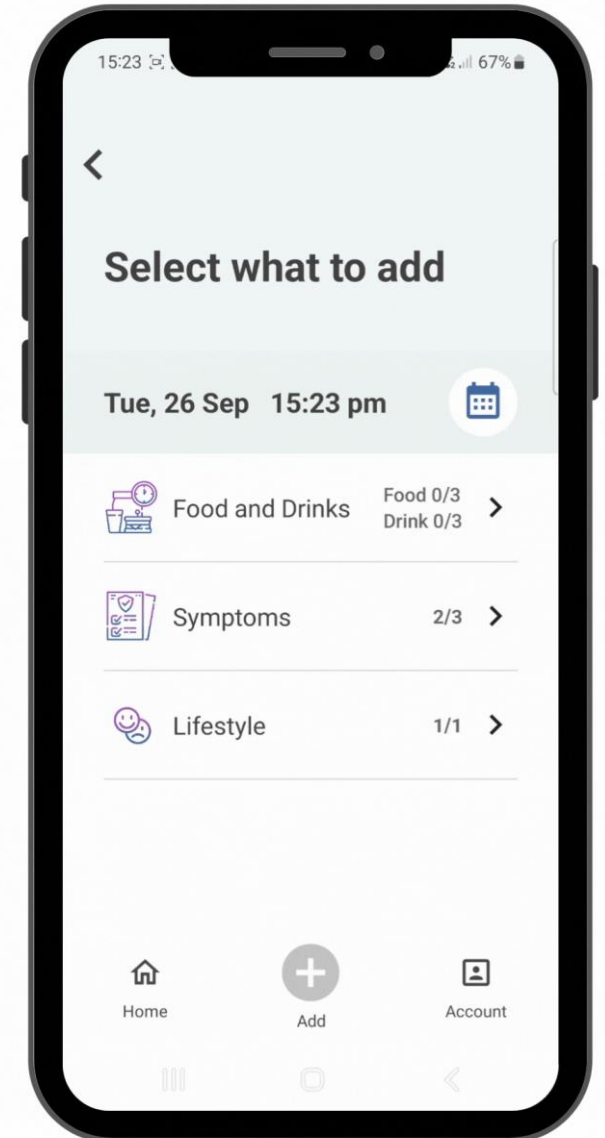
0-10 scores for Bloating, Abdominal Pain, Nausea and Flatulence



Bristol Stool-based scale for Stool records

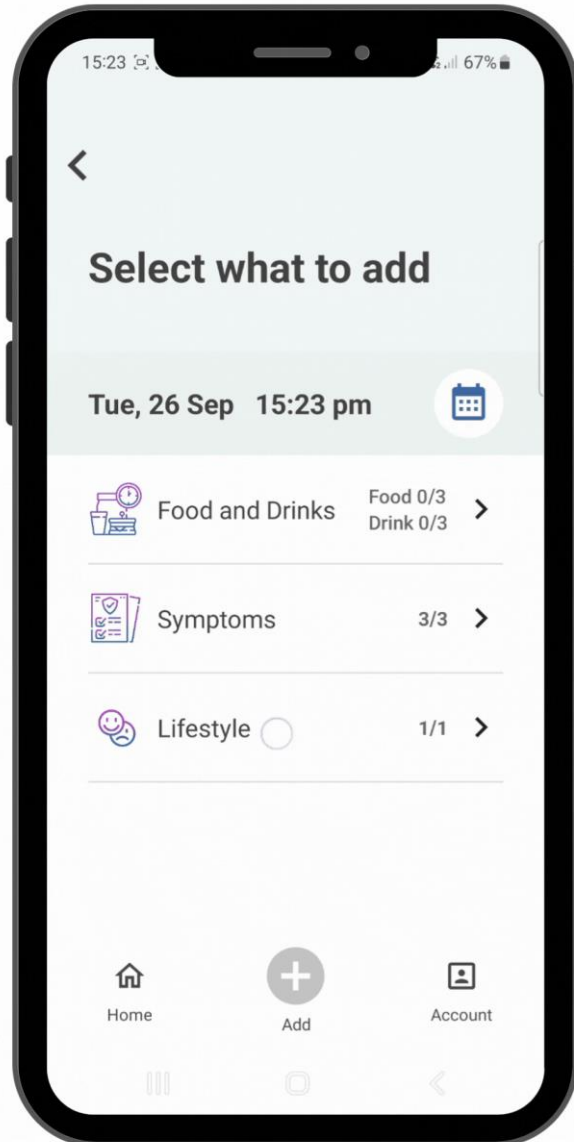


Set the date/time as required over last 14 days





# Record Lifestyle Activities



Use Likert Scale slider bars to record lifestyle activities



0-10 scores for Stress, Sleep Quality and Exercise



Set the date/time as required over last 14 days



## HOME TESTING

- Reduced patient burden, no need to travel to clinic/hospital for testing, no travel costs
- Faster access to results for quicker diagnosis and treatment
- Easier repeat testing while on treatment



## EASY TO USE

- Guided test protocol and data collection within the mobile app, online videos, and telephone support
- Repeat testing, multiple substrates
- Automated data collection and reporting to reduce Practice administrative load
- Engaging mobile app, supported self-management within a care pathway



## SHORTER WAITING LISTS

- Increased clinic/hospital capacity, no limits on testing numbers
- Refocus resources on higher-value activities
- Unattended appointments (no-shows) eliminated



## FLEXIBLE

- Accessibility for patients with limited mobility for travel to clinic/hospital, or in more remote areas
- Facilitating asynchronous communication and adherence to treatment plans, aligned to remote patient monitoring



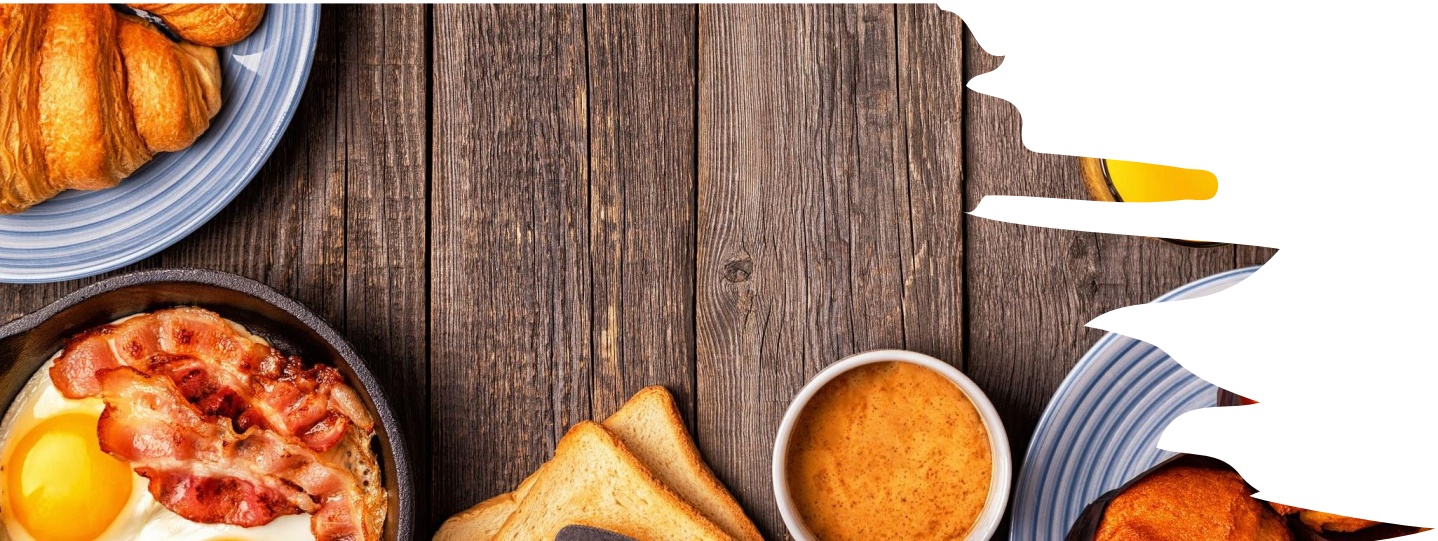
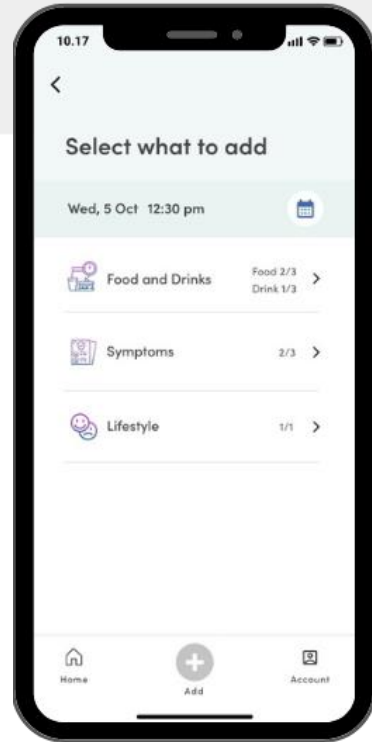
## COST EFFECTIVE

- No need to manage benchtop equipment with associated costs and administrative burden
- Lower repeat testing costs
- Greater patient throughput/increased revenue
- Freeing-up time/space for more complex cases/ other in-clinic/hospital activities



## CONVENIENT

- No need for patients to spend half a day or more at the clinic/hospital
- Access to comprehensive data set to aid diagnosis and more personalized treatment plans



# Treating SIBO

## Antibiotic Therapy

- Rifaximin: Non-absorbable antibiotic targeting gut bacteria.
- Dosage: 550 mg three times daily for 10 to 14 days.
- Mechanism: Reduces bacterial overgrowth without significant systemic effects.
- Clinical Evidence: Multiple studies suggest Rifaximin's efficacy in alleviating SIBO symptoms, but long-term benefits and recurrence prevention

## Dietary Modifications

- Low FODMAP Diet
- Specific Carbohydrate Diet
- Elemental Diet
- Time-Restricted Eating
  
- Low FODMAP diet shows promise in symptom reduction; other diets have varying levels of clinical evidence

## Lifestyle Changes

- Stress management, regular exercise, and adequate sleep support gut health.
- Healthy habits can complement other treatment approaches.
  
- Clinical Evidence: Lifestyle modifications can positively impact gut health and symptom management.

**Herbal Treatments:**

- Natural antimicrobial herbs like oregano oil, berberine, or neem
- Varying evidence; consult a healthcare provider
  
- Clinical Evidence: Limited rigorous research; some studies suggest potential benefits, but more research is needed

**Probiotics:**

Introduction of beneficial bacteria to restore gut microbiota balance

Effectiveness varies; strains should be tailored to individual needs

Clinical Evidence: Limited consensus due to strain variability; some studies indicate potential benefits in symptom management

**Prokinetics:**

Enhance gut motility to prevent bacterial stagnation

Can aid in preventing recurrence

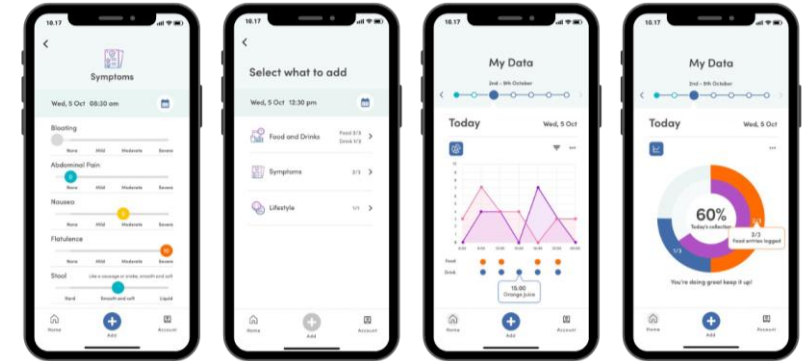
Clinical Evidence: Limited studies on prokinetics for SIBO; potential benefits in certain cases, but more evidence needed

# Specimen Antibiotic (Rifaximin) Course Use Case



## Day 1:

- Download and install the OMED Health companion mobile app on smartphone
- Set up the portable breath analyzer according to the OMED Health instructions
- Familiarization with the app's features, including the ability to record lifestyle factors, symptoms, and a food diary



## Days 1-14:

- Commence 2-week course of Rifaximin as prescribed
- Use the portable breath analyzer to take readings of hydrogen and methane breath levels
- Take one breath readings first thing in the morning (before consuming anything) and then before final meal of the day (having fasted for at least 2 hours beforehand)
- Use the OMED Health companion mobile app to record meals, symptoms, and any other relevant lifestyle information
- On/around day 14, take an at-home HMBT (lactulose challenge) and review test result and longitudinal data collected with the Healthcare Professional



# Example of baseline and longitudinal monitoring of methane

"Fasting SMM  $\geq 10$  ppm seems to accurately diagnose IMO, is associated with constipation, and correlates with stool *M. smithii*. SMM seems to be stable without treatment and decreases after antibiotics. SMM may be a useful test to diagnose IMO and monitor treatment response"

DOI: [10.14309/ajg.0000000000001607](https://doi.org/10.14309/ajg.0000000000001607)

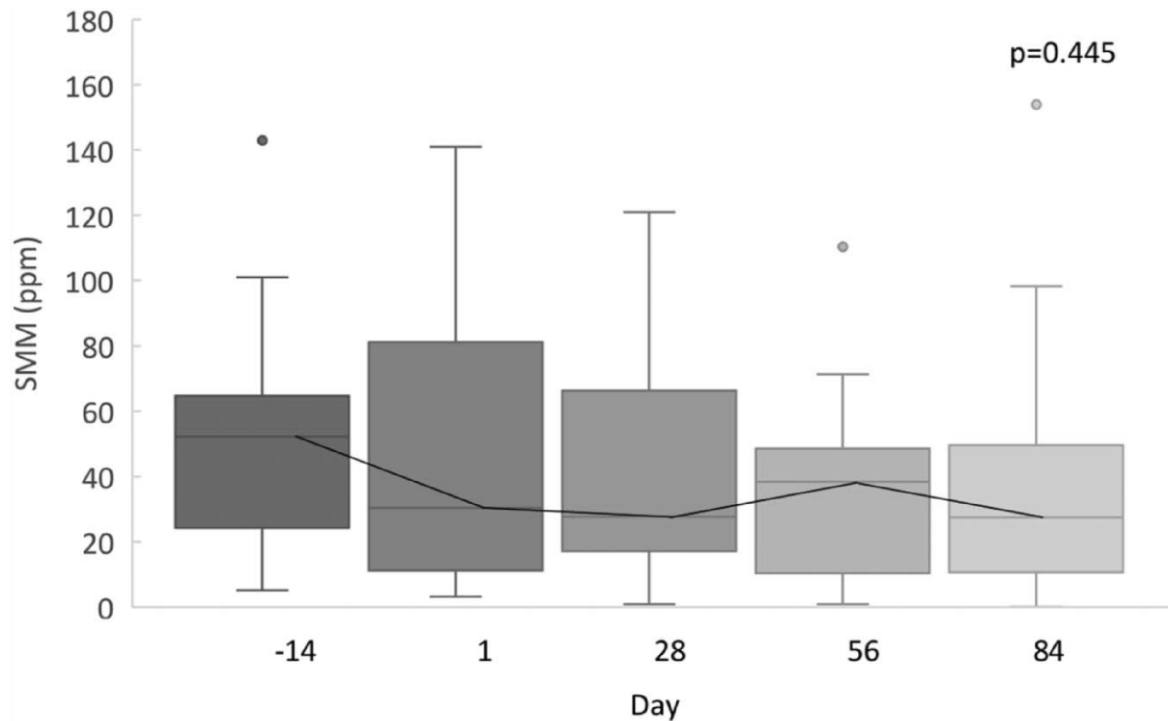


Figure 1: For subjects who received placebo, SMM did not change over time (n = 20).

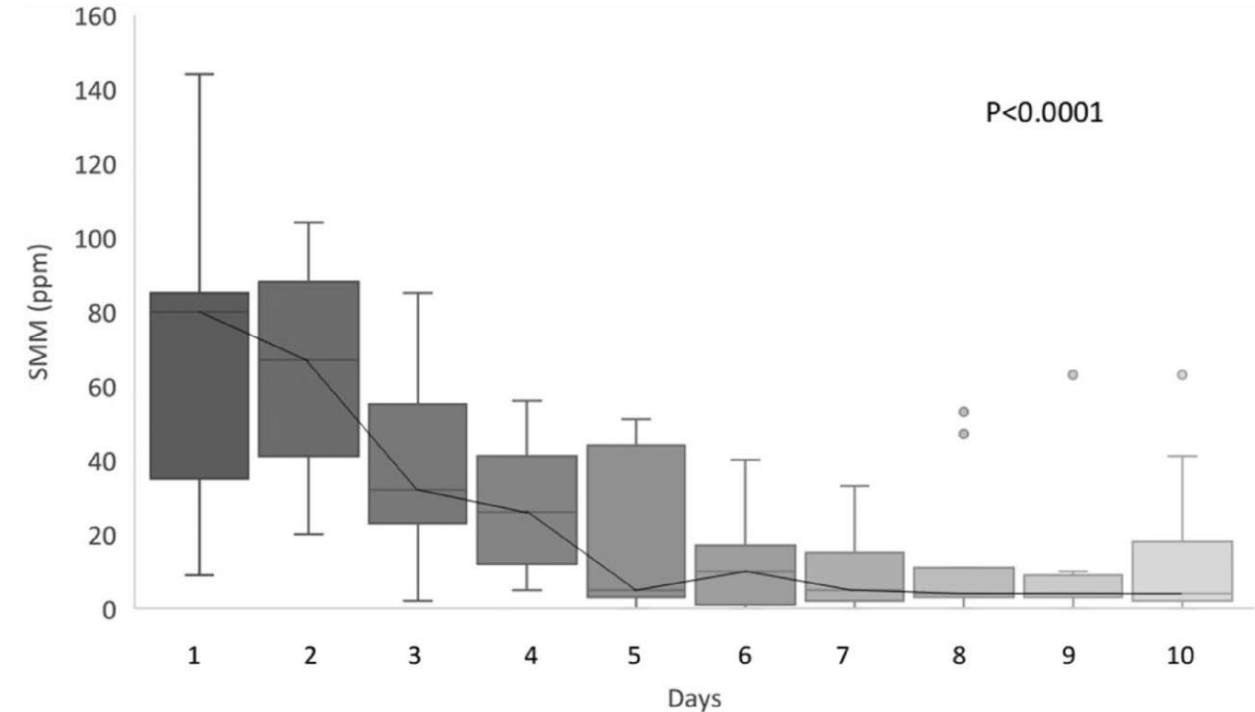


Figure 2: Daily SMM levels rapidly and significantly drop during antibiotic therapy. SMM, single CH<sub>4</sub> measurement.

# Key Points for Specimen Low FODMAP Use Case

## Baseline, Elimination, Reintroduction, Personalisation



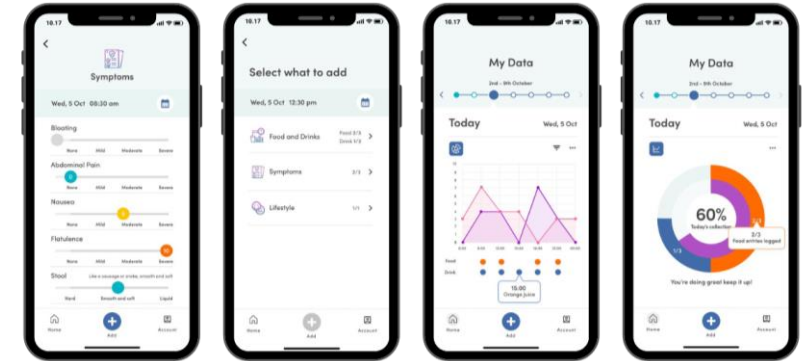
**Breath Analyzer:** Take readings before breakfast and 2 hours after meals to monitor FODMAP responses

**Companion Mobile App:** Record breath readings, symptoms, meals, and lifestyle factors throughout the day

**Dietitian Collaboration:** Regular consultations ensure effective interpretation of data and informed dietary choices

**Personalized Insights:** Identify specific FODMAP triggers to tailor your long-term diet for symptom management

**Seamless Transition:** Information from the Reintroduction Phase informs the next step in the Monash Low FODMAP Diet journey



### Clinical Rationale for Breath Reading Cadence

#### Baseline Measurement:

- Taking a morning breath reading before consuming anything establishes a baseline measurement unaffected by recent meals
- This baseline provides a reference point for assessing FODMAP sensitivities in a fasting state

#### Post-Meal Readings:

- Taking a breath reading 2 hours after each meal captures peak hydrogen and methane levels after digestion
- Allows evaluation of how specific foods influence breath levels, aiding in pinpointing FODMAP sensitivities
- Frequent post-meal readings create a comprehensive view of individualized FODMAP responses throughout the day



# Human People Pilot The IBS-SIBO Solution



## The IBS-SIBO Solution

<https://humanpeople.co/pages/ibs-sibo-solution>  
<https://omedhealth.com/the-ibs-sibo-solution/>

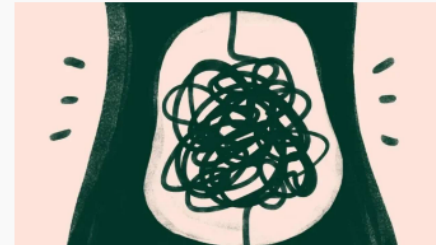
- Step 1: diagnose SIBO - quick & easy
- Step 2: Treat SIBO - "Remove" Phase
- Step 3: Treat SIBO - "Restore" Phase

### Weekly Q&A hosted by our expert team



#### Weekly Q&A hosted by our expert team

Every week we host a group session open to everyone on the course to answer any questions you may...



40 of 57 Lessons Completed

### Module 1: Getting started, testing, and diagnosis

#### Introduction to The IBS-SIBO Solution



#### Welcome to the course

A big warm welcome to The IBS-SIBO Solution, the one-stop shop to beat SIBO quickly and for good...



#### Outline, objectives, and how to get the most from the programme

Each module has been developed to: 1. Diagnose SIBO 2. Treat SIBO 3. Restore and heal the gut pos...



#### Meet your team of medical experts - Dr Geoff Mullan

Meet Dr Geoff Mullan Dr Geoff Mullan is the Chief Medical Officer for humanpeople. A qualified med...

#### The team



**Dr Geoff, Fran and Kirsty**  
UK qualified, CQC registered

Fran is a UK registered and accredited Nutritionist with ANutr mRSPH BDA SCMA. Kirsty is UK registered nutritionists with BANT and IFM and they are both SIBO doctor certified. Dr Geoff Mullan MBBS BSc MRCS is a UK-qualified functional medicine Doctor and Chief Medical Officer at humanpeople. Between us, we have over 30 years of experience in treating gut health.

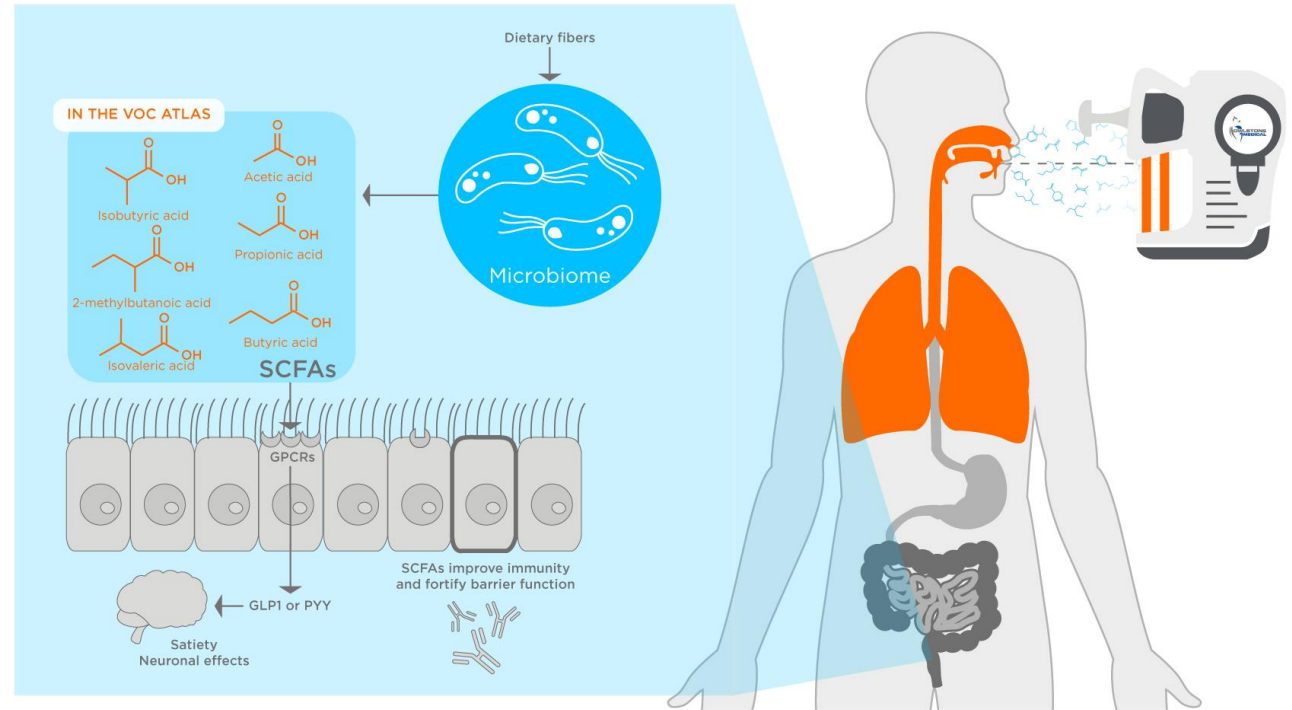


# Owlstone's platform is being used with partners to identify novel microbiome-derived Volatile Organic Compounds (VOCs)

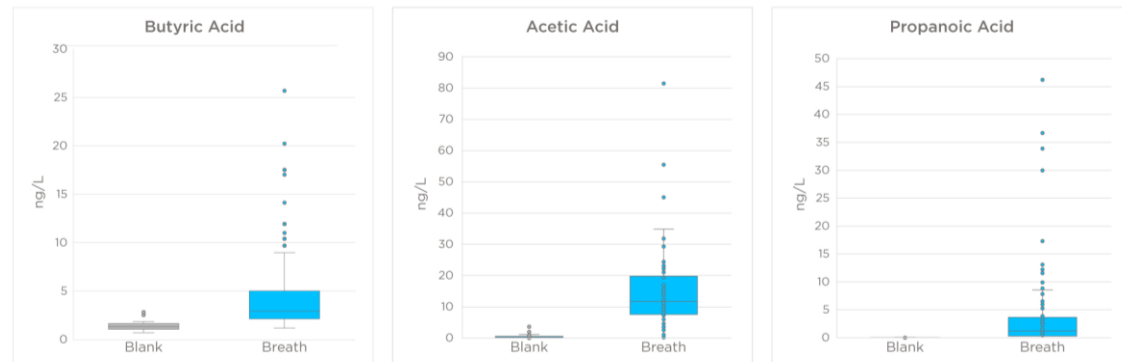


## Breath Biopsy® OMNI®

- The **most advanced solution for volatile metabolite analysis** in breath optimized for biomarker identification and validation
- Supported by the **Breath Biopsy VOC Atlas**, a unique catalog of identified VOCs commonly found on-breath
- **Expert support** on study design, project management, and data interpretation
- Promising microbiome-derived VOCs include **Hydrogen Sulphide** and **Short-Chain Fatty Acids (SCFA)**



## Microbiome derived VOCs are detectable on breath with the Breath Biopsy Platform



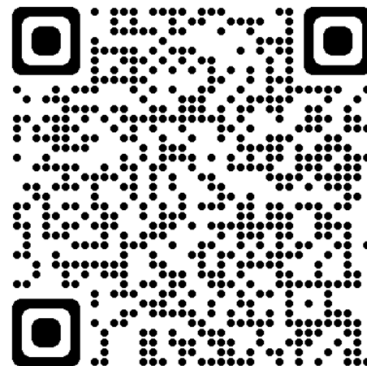
# OMED device for your patients?

## Gut health breath tests

- Portable, low cost, easy to use and accurate measurement of hydrogen and methane.
- Giving healthcare professionals better data to support the development and monitoring of personalized plans.
- Useful for your patients?



OMED device  
pre-order link





THANK YOU

[omedhealth.com](http://omedhealth.com)

  OMED Health