Non-invasive breath analysis for the detection of gastrointestinal disorders with the Gastrolyzer®

CE 2797

BRITISH TECHNOLOGY

Helping to detect gastrointestinal disorders, one breath at a time.

www.gastrolyzer.com

bedfont

Contents

Hydrogen Breath Testing (HBT)

HBT is a non-invasive, and specific means of diagnosing small bowel sugar malabsorption. HBT makes use of gut bacteria's ability to digest sugars and convert these to hydrogen, which is then absorbed into the blood and can be measured in exhaled breath[1].

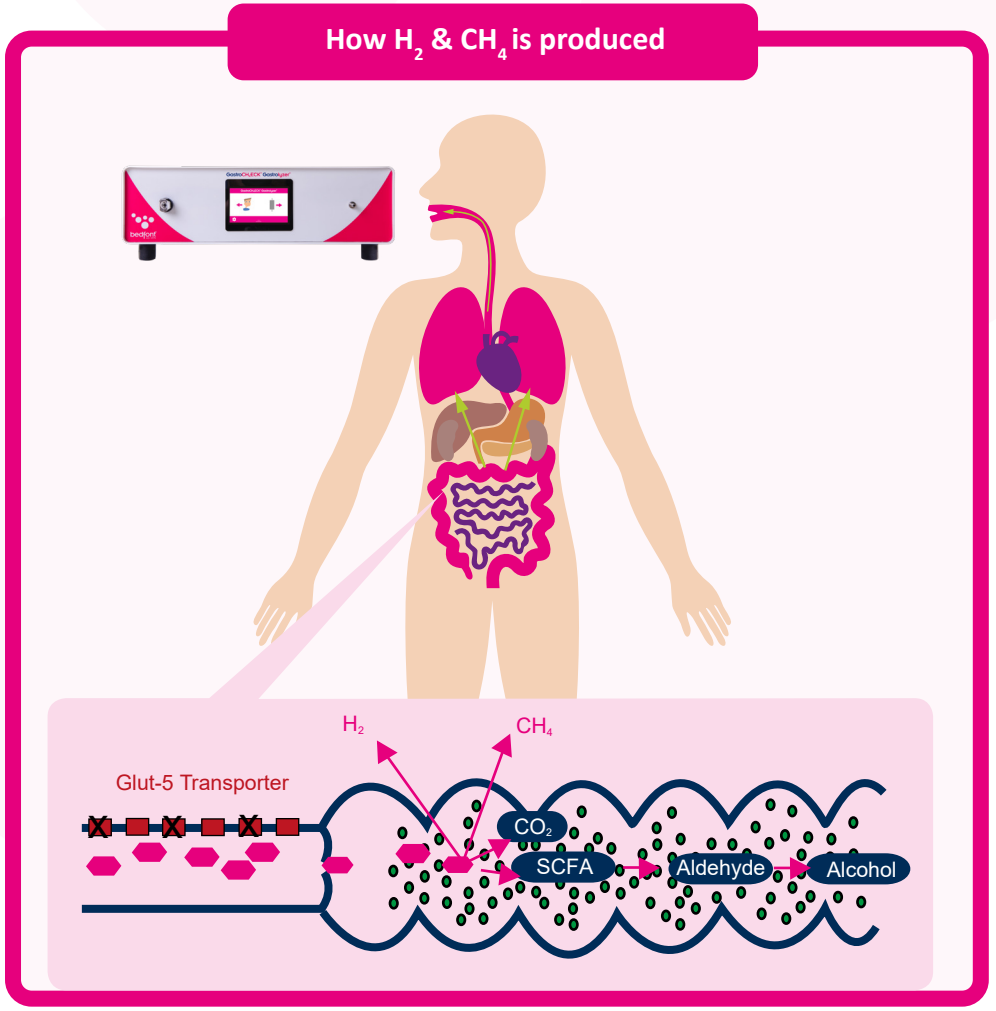
The test is commonly used in paediatric and adult gastroenterology departments to diagnose malabsorption of the sugars lactose, fructose and sucrose. It is also used to investigate small intestinal bacterial overgrowth (SIBO)[2].

The Gastrolyzer® range is world renowned for delivering accurate hydrogen breath testing, cited by clinical leaders in gastroenterology, such as Robert Heuschkel[3] and Way Seah Lee[4].

The role of Methane alongside Hydrogen Breath Testing (HMBT)

A percentage of patients do not produce hydrogen and therefore would not be diagnosed by the use of HBT alone. The role of GastroCH$_4$ECK® is to ensure that patients who are non-hydrogen producers, but produce methane or a combination of both, are not misdiagnosed.

"Medical literature shows that the level of methane producers varies by gender and population group, from approximately 33-41%[5,6,7]"



Gastro+™ Gastrolyzer®

Portable breath Hydrogen monitoring to help diagnose gastrointestinal disorders.

Aids in the detection of:

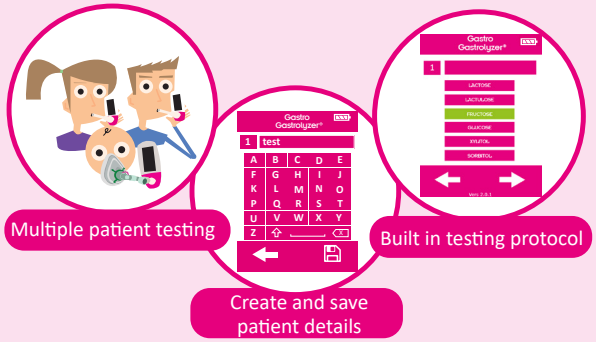
- Food intolerances
- Irritable Bowel Syndrome (IBS)
- Small Intestinal Bacterial Overgrowth (SIBO)

FREE
GastroCHART™ software

ANTIMICROBIAL TECHNOLOGY

Ideal for:

- Gastroenterologists
- Gastro paediatricians
- Dieticians
- GP's
- Endoscopy departments



The easy to use, complete breath Hydrogen device with 2 sampling modes.

Face mask sampling system

This sampling system is recommended for use with younger or older patients who are unable to cooperate with the test. The Gastro+™ is attached to a face mask, which is then placed over the mouth and nose of the patient. Once 'face mask' mode is selected, the Gastro+™ will take a real-time reading until the result stabilises. The reading is then held on the screen and can then be saved to a patient profile, downloaded to the GastroCHART™ database or recorded manually.

Mouthpiece sampling system

This sampling system is recommended for use with adults or patients able to hold their breath for a short period of time. The patient takes a deep breath in, holds, then exhales slowly through a mouthpiece. Within 45 seconds their result will be displayed on the screen and can then be saved to a patient profile, downloaded to the GastroCHART™ database or recorded manually.

Features and benefits

- Easy to use interface
- Maintenance reminders
- Only needs calibrating every 3 months
- Create and store patient details
- Multiple patient testing
- Built in testing protocols with built in countdown timer
- Large touchscreen
- Antimicrobial technology for improved infection control
- Comes with GastroCHART™ software

Technical Specification:

Concentration range	0 - 500 ppm
Display	Full colour touchscreen
Detection principle	Electrochemical sensor
Repeatability	< 5%
Accuracy	≤ ± 3 ppm / 10% - whichever is greater*
Power	3 x AA (LR6 or equivalent) – up to 1000 minutes 1 x CR2032 Lithium coin cell
T_{90} response time	< 40 seconds
Operating temperature	15 - 35°C
Storage/transport temperature	0 - 50°C
Operating/storage/transort pressure	Atmospheric ± 10%
Operating humidity	15 - 90% non-condensing
Storage/transport humidity	0 - 95%
Sensor operating life	2 years
Sensor sensitivity	1 ppm
Sensor drift	< 2% per month
Dimensions	Approx. 37 x 77 x 140 mm
Weight	Approx. 215 g (including batteries)
Materials	Case: polycarbonate/ABS blend Antimicrobial additive D-piece™: polypropylene SteriBreath™ Eco: Paper OneBreath™ Mouthpiece: polypropylene
CO cross interference	< 4%

* Readings of > 200 ppm at temperature between 26 - 35°C can decrease accuracy to 15%.

Consumables

SteriBreath™ Eco mouthpiece: SteriBreath™ Eco mouthpiece is entirely made from paper and therefore it is 100% recyclable and 100% biodegradable, including its packaging. Even better, all the materials are from sustainable sources.

Order code: STERIBREATH-ECO (200 per box)

D-piece™: The D-piece™ is used to attach a SteriBreath™ mouthpiece to the device. The D-piece™ incorporates a one-way valve and an infection control filter, which are proven to remove and trap > 99% of airborne bacteria and > 97% of viruses[8].
The D-piece™ should be changed every 4 weeks, an automatic reminder will appear on the screen every 28 days.

Order code: D-PIECE-3 (12 per box)

OneBreath™ mouthpieces: The OneBreath™ mouthpiece is a single-use bacterial filter mouthpiece and can be attached directly to the device to take a breath sample. The OneBreath™ incorporates a one-way valve and an infection control filter, which are proven to remove and trap > 99% of airborne bacteria and > 97% of viruses[8].

Order code: ONEBREATH-MP (250 per box)

Face mask sampling system: This sampling system is single patient use and allows the patient to breathe normally through a face mask in order to produce a breath sample.

Order code: ISSA-V-2 (1 sampling kit)

Small face mask
Suitable for use with infants. **Order code:** EC60-IM-V

Medium face mask
Suitable for use with adolescent. **Order code:** EC60-MM-V

Large face mask
Suitable for use with adults. **Order code:** EC60-AM-V

Calibration kit: The Gastro+™ requires calibration every 3 months using 100 ppm H_2 gas, provided as a kit or replacement cylinder.

Order code: 012-14-12010K-V (kit)
012-14-12010-V (replacement cylinder)

GastroCH$_4$ECK® Gastrolyzer® features

Accurate and real-time combined CH_4, H_2, and O_2 monitoring.

GastroCH$_4$ECK® Gastrolyzer®

Hydrogen and methane monitoring to aid in the diagnosis of gastrointestinal disorders.

The GastroCH$_4$ECK® is a portable breath CH_4, H_2 and O_2 device, which allows health professionals to accurately detect a range of gastrointestinal disorders. An O_2 reading is taken to motivate patients to provide an end-tidal sample. If the sample is not adequate, the GastroCH$_4$ECK® will automatically correct the reading, saving the patient from embarrassment and eliminates the need to carry out another test.

Applications

The GastroCH$_4$ECK® can be used as an aid to diagnose the following disorders:

- Carbohydrate breakdown deficiency
- Carbohydrate malabsorption
- Lactose intolerance
- Bacterial overgrowth
- Determination of time passage through gut
- Irritable bowel syndrome (IBS)

Features/benefits

- Direct breath sampling line for instant results
- Breath bag sampling for simultaneous testing of larger groups
- Requires calibration just once a month, saving time and calibration gas costs
- Full-colour touchscreen
- Intuitive interface
- No warm-up time
- Maintenance reminders
- Service diagnostic management
- FREE GastroCHART™ software

"Medical literature shows that the level of methane producers varies by gender and population group from approximately 33-41%[5,6,7]"

"If you are serious about providing a gold-standard breath testing service, the Bedfont® GastroCH$_4$ECK® system is essential, as without methane monitoring you will be missing very important clinical information and increase your percentage of false negative tests. It is also very important to map patients symptoms prior to and during the test to make sure the clinical translation of the physiological findings are maximised."

Dr Anthony Hobson from The Functional Gut Clinic, London, UK.

GastroCH$_4$ECK® Technical Specification:

Concentration range	CH_4		0 - 200 ppm
	H_2		0 - 200 ppm
	O_2		14 - 23%
Power input			230 V/100 V, 50 Hz - 60 Hz, 0.5 - 1.0 A
Fuse			T 3.15 AH
Calibration frequency			Every 4 weeks
Start-up time			≤ 2 minutes
Display			Full colour touchscreen
Detection principle			Electrochemical sensor (O_2 & H_2) Laser (CH_4)
Accuracy	CH_4	Resolution	1 ppm
		Accuracy	± 10% of reading
		Repeatability	< 5% difference on consecutive readings
	H_2	Resolution	1 ppm
		Accuracy	± 10% of reading
		Repeatability	< 5% difference on consecutive readings
	O_2	Resolution	0.1%
		Accuracy	± 10% of reading
		Repeatability	< 5% difference on consecutive readings
Carbon monoxide cross-sensitivity (H_2 only)			< 4%
Temperature range	Operating		15 - 35°C (59°F - 95°F)
	Storage		0 - 40°C (32°F - 104°F)
Pressure range	Operating		912 - 1114 mbar (Atmospheric ± 10%)
	Storage		912 - 1114 mbar (Atmospheric ± 10%)
Humidity range	Operating		30 - 75% RH (non-condensing)
	Storage		15 - 90% RH (non-condensing)
Sensor operating life	CH_4		5 years
	H_2		2 years
	O_2		2 years
Dimensions			Approx. 474 x 310 x 135 mm
Weight			Approx. 8.5 kg
Monitor construction			Case: aluminium
Classification			Class I ME equipment: (externally powered) Type BF applied part Method of sterilization (not suitable for sterilization) Not suitable for use in an oxygen rich environment Intended for continuous use
Response time			≤ 45 seconds
Warranty	GastroCH$_4$ECK® without sensors		2 years
	CH_4, H_2 and O_2 sensors		1 year

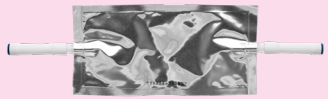
 * Subject to maintenance and service.

GastroCH$_4$ECK® Consumables

GastroCH$_4$ECK® mouthpieces: specifically designed with the latest moisture removal and bacterial filtration to remove 99.9% of airborne bacteria from the patient's breath[8]. GastroCH$_4$ECK® mouthpieces are 'per patient use' so can be used for the duration of a patient's testing procedure and disposed of. DO NOT REUSE AFTER THE 1ST DAY OF TESTING.

Order code: GASTROCHECK-MP-XL (box of 250)

GastroCH$_4$ECK® breath bags: specifically designed to capture as much end-tidal air as possible, with a one-way mouthpiece to prevent loss of sample. GastroCH$_4$ECK® breath bags are 'per patient use' so can be used for the duration of a patients testing procedure and disposed of. DO NOT REUSE AFTER THE 1ST DAY OF TESTING.



Order code: GASTROCHECK-BAG-XL (250 breath bags and bag mouthpieces)

Face mask sampling system: this sampling system is single patient use and allows the patient to breathe normally through a face mask in order to produce a breath sample. For use with breath bags.

Order code: ISSA-BB (1 sampling kit)

Small face mask
Suitable for use with infants. **Order code:** EC60-IM-V

Medium face mask
Suitable for use with adolescent. **Order code:** EC60-MM-V

Large face mask
Suitable for use with adults. **Order code:** EC60-AM-V

Moisture removal filters: for use with the breath bag sampling mode. These will last for approximately 150 samples and need to be changed when the filter changes from orange to dark green.

Order code: GASTROCHECK-DESS-XL (pack of 5 moisture removal filters)

Calibration kit: the GastroCH$_4$ECK® requires calibration once per month using 100ppm H_2, 100 ppm CH_4 & 20.9% air provided as a kit or replacement cylinder.

Order code: GASTROCHECK-CAL-KIT
GASTROCHECK-CAL -(Replacement cylinder)

GastroCHART™ patient database (included with every Gastro+™ & GastroCH4ECK®)

The GastroCHART™ is designed specifically for use with the Gastro+™ and GastroCH4ECK®. With the Gastro+™, the software is integrated and allows the health professionals to save up to 10 patients on the device for satellite breath tests. If the Gastro+™ or GastroCH4ECK® are connected to a PC, readings can be downloaded to an unlimited patient database immediately. The readings can then be shown in tabular format or in a graph to show whether the patient has presented a positive/negative result. Results can be easily printed for the patient to retain and for record in their medical history.

References

1. Ledochowski, M. and Ledochowski, L. (2011) Hydrogen Breath Tests. 2nd Edition edn. Austria: Verlag Akademie für Ernahrungsmedizin GmbH.
2. Eisenmann, A., Amann, A., Said, M., Datta, B. and Ledochowski, M. (2008) 'Implementation and interpretation of hydrogen breath tests',Journal of Breath Research, 2(4), p.046002.
3. Shelley, H., Brennan, M. and Heuschkel, R. (2009) 'Hydrogen breath testing in children: What is it and why is it performed?',Gastrointestinal Nursing, 7(5), pp. 18–27
4. Lee, W., Davidson, G., Moore, D. and Butler, R. (2000) 'Analysis of the breath hydrogen test for carbohydrate malabsorption: Validation of a pocket-sized breath test analyser', Journal of Paediatrics and Child Health, 36(4), pp. 340–342.
5. Roccarina, D., Lauritano, E. C., Gabrielli, M., Franceschi, F., Ojetti, V. and Gasbarrini, A. (2010) 'The role of methane in intestinal diseases', The American Journal of Gastroenterology, 105(6), pp. 1250–1256.
6.Pitt, P., de Bruijn, K. M., Beeching, M. F., Goldberg, E. and Blendis, L. M. (1980) 'Studies on breath methane: The effect of ethnic origins and lactulose', Gut, 21(11), pp. 951–954.
7.Di Stefano, M. and Corazza, G. R. (2009) 'Role of hydrogen and methane breath testing in gastrointestinal diseases', Digestive and Liver Disease Supplements, 3(2), pp. 40–43.
8. Public Health England. An Evaluation of Filtration Efficiencies Against Bacterial and Viral Aerosol Challenges Report No. 17/001(091.010). London: Public Health England; 2017

Join the Gastrolyzer® forum today

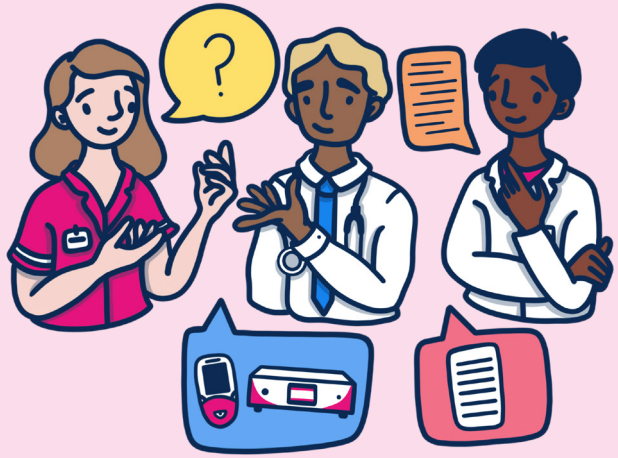
Did you know purchasing this product entitles you to free membership of the Gastrolyzer® email forum...

What is the Gastrolyzer® email forum?

It is an international, invitation only forum where professionals using the Bedfont® Gastrolyzer® range of devices can communicate and share knowledge.

There is no cost or obligation to participate but membership is free when you purchase a Bedfont® Gastro+™ or GastroCH4ECK® Gastrolyzer® - take advantage and join this exclusive group today!

For more information, please contact forums@bedfont.com.



How does it work?

Signing up is simple and only requires your full name and email address. We will then contact you for your Gastrolyzer® serial number.

Email forums@bedfont.com for more information.

Contact Bedfont® or one of our worldwide Gastrolyzer®
distributors for a free demonstration.

www.bedfont.com
Tel:+44 (0)1622 851122
E-mail: ask@bedfont.com

Visit www.bedfont.com/resources to view this document in other languages.

Our family, innovating health, for yours.

Bedfont® Scientific Ltd.
Station Road, Harrietsham, Maidstone,
Kent, ME17 1JA England
Tel: +44 (0)1622 851122 Fax: +44 (0)1622 854860
Email: ask@bedfont.com Web: www.bedfont.com

Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands.

Issue 10 - September 2024, Part No: MKT151_AX
Bedfont® Scientific Limited reserve the right to change or update this literature without prior notice.
Registered in: England and Wales. Registered No: 1289798

MD 502905