GastroCH$_4$ECK® Gastrolyzer®

USER MANUAL

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

Definitions

WARNING: indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury.

CAUTION: indicates a potentially hazardous situation, which, if not avoided, may result in damage to the device.

NOTE: used to call attention to notable information that should be followed during use.

Important Information/Reminders

WARNING: Please read the manual before use.

WARNING: Breath tests must only be carried out with Bedfont® accessories. Failure to do so may cause incorrect readings.

WARNING: The mouthpieces are single patient use only. Further re-use could cause incorrect readings and could increase the risk of cross infection which may result in decreased accuracy of results. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.

WARNING: Do not open the GastroCH$_4$ECK® Gastrolyzer®, this could result in bodily harm.

WARNING: Never use alcohol, substances containing alcohol, or other organic solvents as these vapours will damage the sensors.

WARNING: Under no circumstances should the device be immersed or splashed with liquid.

WARNING: To reduce the risk of electrical shock, this device uses a three-wire electrical cord and plug to connect the GastroCH$_4$ECK® Gastrolyzer® to earth-ground.

WARNING: Fuses protect certain electrical circuits within the GastroCH$_4$ECK® Gastrolyzer® against overcurrent conditions.

WARNING: For continued protection against the risk of fire, replace only with the same type and rating specified.

WARNING: Only fuses with the following ratings should be applied: 250Vac, 3.15AH T, 1500A breaking capacity.

WARNING: The GastroCH$_4$ECK® Gastrolyzer® is not designed for use with materials capable of developing flammable or explosive vapours.

WARNING: If the GastroCH$_4$ECK® Gastrolyzer® is used in a manner other than that specified in this manual, the safety and performance of this device could be impaired. Further, the use of any device

other than that recommended by Bedfont® has not been evaluated for safety. Use of any device not specifically recommended in this manual is the sole responsibility of the user.

WARNING: When selecting an accessory for the GastroCH$_4$ECK® Gastrolyzer® device, please be advised that an accessory not recommended by Bedfont® may result in loss of performance and may compromise the safety of the device.

CAUTION: Do not use hand sanitising products containing alcohol as this may damage the sensors.

CAUTION: The GastroCH$_4$ECK® should not be operated in an environment outside of the temperature or humidity ranges stated in the technical specification.

CAUTION: The GastroCH$_4$ECK® should be switched off once every 24 hours.

CAUTION: Portable and mobile RF communications device can affect the GastroCH$_4$ECK® Gastrolyzer®.

CAUTION: Sensor use beyond the specified component lifetime without servicing may compromise result accuracy.

CAUTION: Use only accessories designed for use with the GastroCH$_4$ECK® Gastrolyzer®.

CAUTION: Please do not attempt to modify the device in any way or use accessories not specified by the manufacturer. Any attempt to do so, will invalidate the warranty and may cause product failure or damage to your GastroCH$_4$ECK® Gastrolyzer® device. The product warranty does not cover product failure or damage resulting from use with non-approved accessories.

NOTE: The device should be calibrated prior to first use, after transportation, and every 4 weeks.

NOTE: Please allow the GastroCH$_4$ECK® to be switched on for at least 5 minutes prior to calibration.

NOTE: The GastroCH$_4$ECK® device temperature needs to be at 21°C ± 4°C (69.8°F ± 39.2°F) to be able to perform a calibration.

NOTE: Bedfont® recommends an annual service in order to check sensor and component parts performance.

NOTE: Servicing should only be carried out by a Bedfont® trained representative

NOTE: Bedfont® will make available on request service training to appropriately qualified personnel.

NOTE: Please refer to Bedfont's infection control and maintenance guidelines for further information on infection control.

Contents

Introduction

The User Manual provides instructions on how to operate GastroCH$_4$ECK® Gastrolyzer® and its accessories. It contains relevant information about the device, its uses and its care, including step-by-step instructions with screens and illustrations.

Intended Use

The GastroCH$_4$ECK® Gastrolyzer® is a portable desktop device used to measure Hydrogen (H_2), Methane (CH_4) and Oxygen (O_2) levels in expired breath samples as an aid to screening and diagnosis of gastrointestinal sugar and nutrient malabsorption.

The GastroCH$_4$ECK® Gastrolyzer® is intended for multi-patient use by children and adults, measuring expired breath samples acquired via a breath-bag for remote testing or using the mouthpiece and sample line.

The GastroCH$_4$ECK® Gastrolyzer® analyses a single patient sample at a time, interfacing with a PC to allow a multi-patient sampling protocol to be performed and allowing further analysis of multiple results by an appropriately qualified healthcare professional.

The GastroCH$_4$ECK® Gastrolyzer® can be used as an aid in the screening and diagnosis of the following disorders:

- Carbohydrate Breakdown Deficiency
- Carbohydrate Malabsorption
- Lactose Intolerance
- Bacterial Overgrowth
- Determination of time of passage through gut

The GastroCH$_4$ECK® Gastrolyzer® diagnostic measurements obtained are intended to be reviewed by an appropriately qualified healthcare professional and interpreted in conjunction with relevant medical factors applicable to the sample provider, as an aid in assessment of appropriate treatment or an aid to diagnosis of a condition. Specific diagnosis is not possible directly or instantly with this device; further specific testing and symptom analysis would need to be carried out by a healthcare professional to diagnose a patient's condition.

Contraindications

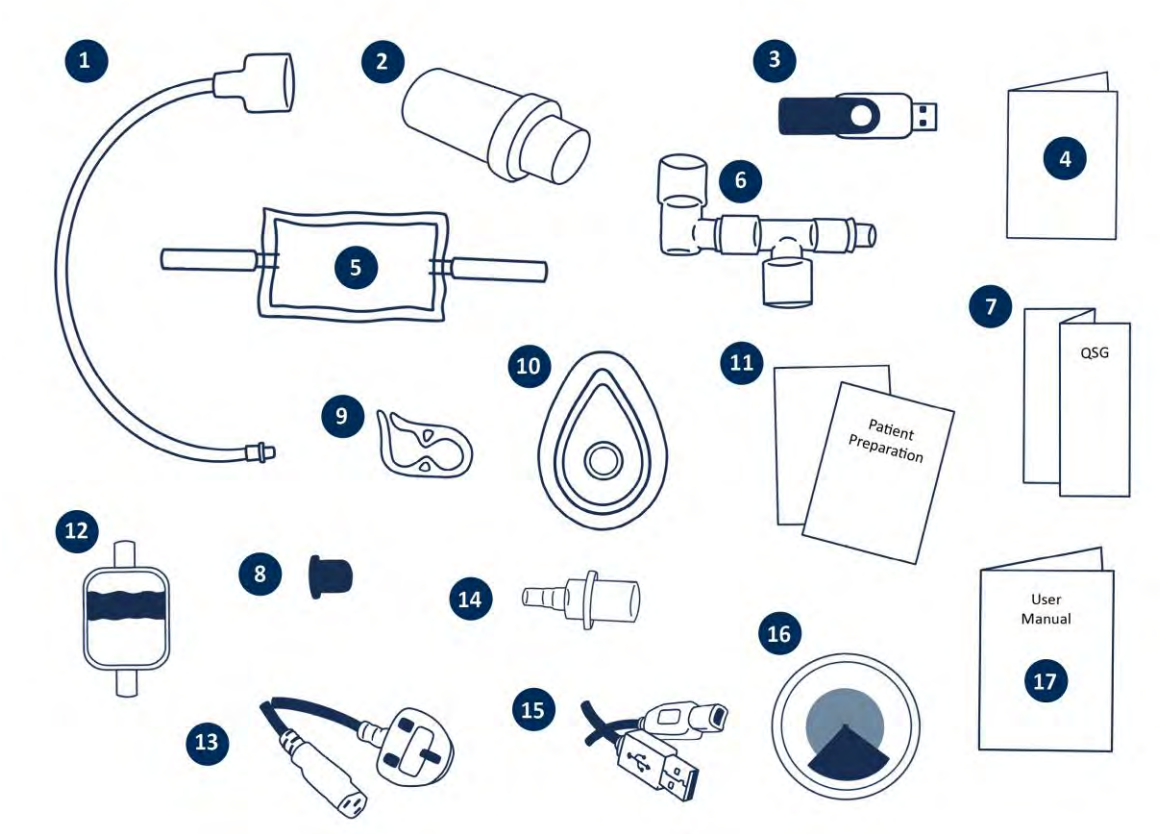
There are no known contraindications.

Compliance

Please refer to the following sections of this manual for more information on the compliance of the GastroCH$_4$ECK® Gastrolyzer® device

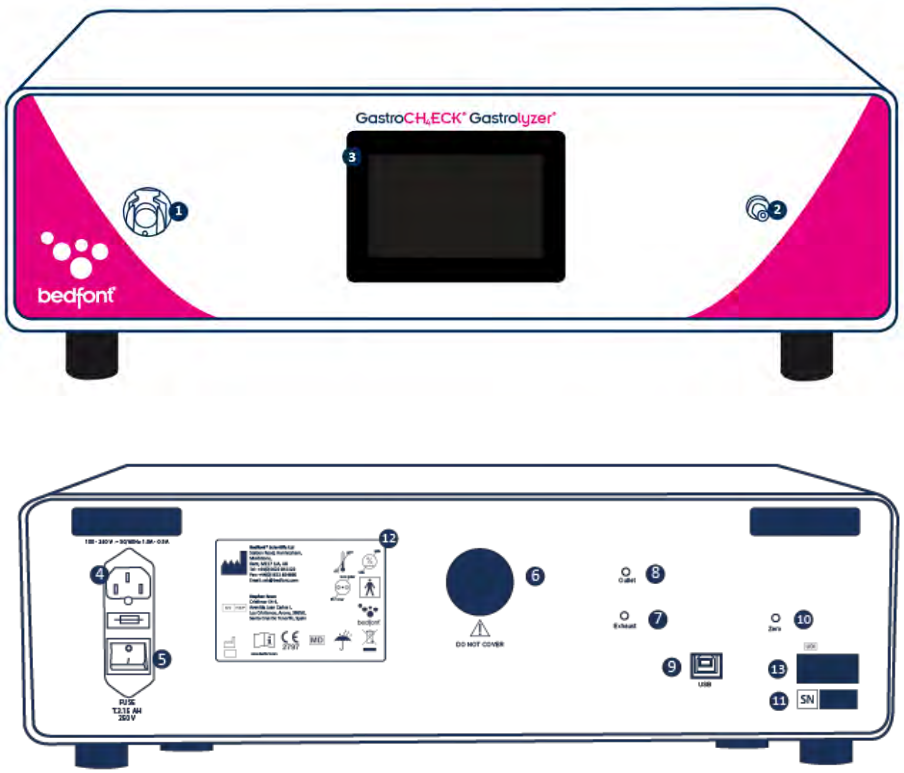
- Glossary of Symbols and Safety Information
- Environment

Parts and Accessories



1. Direct sampling line
2. Mouthpiece
3. USB with GastroCHART™ software
4. Hydrogen Breath Tests book by Ledochowski
5. Breath bag
6. Sampling system
7. Quick Start Guide
8. Blue plugs
9. Breath bag clip
10. Face mask
11. Patient Preparation document
12. Moisture filter
13. Power cable
14. Breath bag mouthpiece
15. USB cable
16. Interpretation wheel
17. User Manual

Instrument Layout



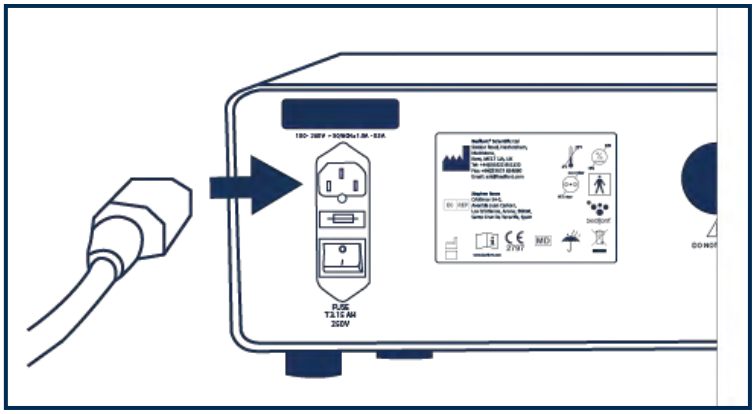
1. Sample line port
2. Breath bag port
3. Full-colour touchscreen
4. Mains power inlet
5. ON/OFF switch
6. Cooling fan
7. Exhaust
8. Outlet
9. USB port
10. Zero
11. Serial Number
12. Manufacturer label

Installation and Set-up

NOTE: *The device should be calibrated prior to first use, after transportation, and every 4 weeks.*

CAUTION: The GastroCH$_4$ECK® should not be operated in an environment outside of the temperature or humidity ranges stated in the technical specification.

1. Place the GastroCH$_4$ECK® on a level surface with a 30cm (1ft) clearance envelope for ventilation.
2. Connect the power cable to the GastroCH$_4$ECK® via the socket on the rear of the device and plug the other end into the mains.

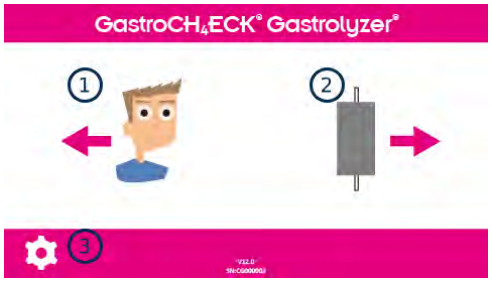


3. Switch the device on using the ON/OFF switch at the back of the device. The screen will light up and if any warning screens are displayed, these should be checked in the Troubleshooting section of the manual.

WARNING: When selecting an accessory for the GastroCH$_4$ECK® Gastrolyzer® device, please be advised that an accessory not recommended by Bedfont® may result in loss of performance and may compromise the safety of the device.

WARNING: The mouthpieces are single patient use only. Further re-use could cause incorrect readings and could increase the risk of cross infection which may result in decreased accuracy of results. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.

User Interface



Home Screen

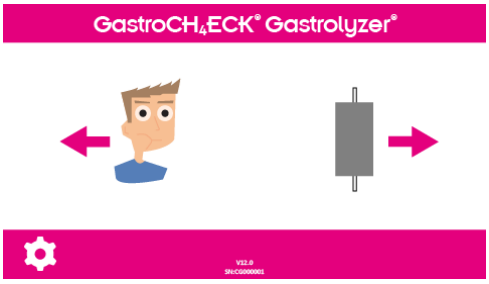
1. Start Breath Test button
2. Start Bag Test
3. Go to Settings Menu

Settings Menu

1. Go to Diagnostic Page
2. Start Calibration procedure
3. Go to Service Area
4. Home Button

NOTE: *The Service Area is PIN protected and must only be accessed by trained personnel:*

Breath Testing



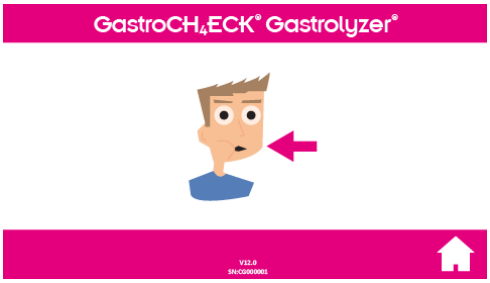
Attach the sample line to the GastroCH$_4$ECK® via the sample connecter.

Then attach a new mouthpiece to the other end of the sample line.

Press the breath test icon to begin.

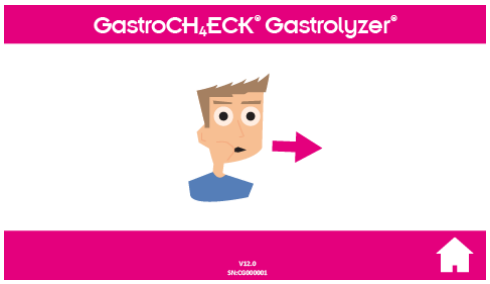
A timer will be shown onscreen whilst the sensors are zeroing. This may take up to 75 seconds if a test has just been carried out.

NOTE: *If GastroCHART™ is being used to record the readings, on the patient's profile click 'capture reading' now.*



The inhale symbol will be shown onscreen for 3 seconds, to prompt the user to take a deep breath.

The timer screen will be shown to prompt the user to hold their breath for the 15 second countdown.



A beep will sound during the last three seconds of the countdown.

Exhale slowly into mouthpiece when prompted onscreen.

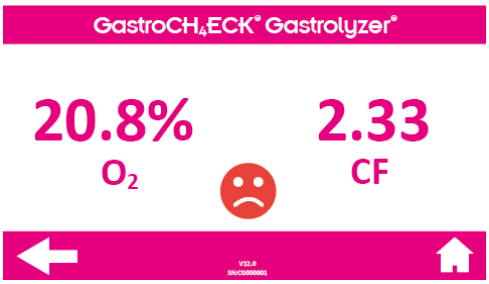
An on-screen dial will help to guide the exhalation rate; keep the arrow pointing in the green section of this indicator throughout the test.

The arrow will change colour as the O_2 level in the breath sample reduces to the target 15%, at which point it will turn green and the test will automatically stop after 3 seconds.

NOTE: *If the patient is unable to exhale for any longer, the test can be ended early by pressing END.*

The results will be shown onscreen.

Once the test is complete, the final O_2 concentration can be observed by pressing the question mark.



This will show the O_2 concentration in % and the correction factor applied to the reading if it was required. A visual indicator will help to interpret the result:

a. Good test, little or no correction factor applied
b. Satisfactory test, correction factor applied
c. Poor test, high correction factor applied and another test is recommended

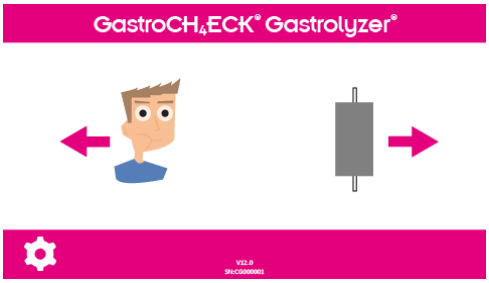
Press the back arrow to return to the results screen.

When finished, press 'HOME' to return to the home screen.

NOTE: *This will lose the reading; please ensure the results have been downloaded to GastroCHART™ or have been recorded manually.*

Remove the mouthpiece and sample line between tests to purge sensors with fresh air.

Analysing a Breath Bag Test



Attach the moisture filter to the device via the bag sample connector.

Press the breath bag icon to start the bag test procedure.

The device will then illustrate to attach the breath bag. Carefully remove the blue plug on one end only and attach the bag to the moisture filter, then open the clamp on that end only to preserve the sample.

Press the arrow to continue.

A timer will be shown onscreen, whilst the sensors are zeroing. This may take up to 75 seconds if a test has just been carried out.

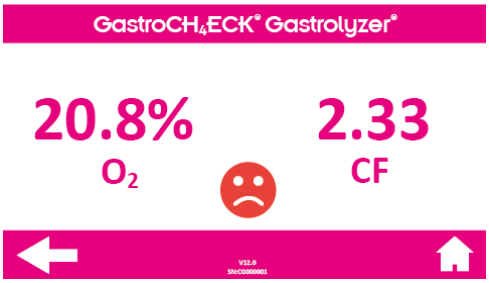
NOTE: *If GastroCHART™ is being used to record the readings, on the patient's profile click 'capture reading' now.*

Once zeroed, breath bag sampling will begin automatically – make sure that the clamp is open. At this point, the device needs no further intervention until a reading is recorded.

The device will draw the breath sample for analysis; this will take 45 seconds, as indicated on the screen.

The results will be shown onscreen.

Once the test is complete, the final O_2 concentration can be observed by pressing the question mark.



This will show the O_2 concentration in % and the correction factor applied to the reading if it was required. A visual indicator will help to interpret the result:

a. Good test, little or no correction factor applied
b. Satisfactory test, correction factor applied
c. Poor test, high correction factor applied and another test is recommended

When finished, press 'HOME' to return to the home screen.

NOTE: *This will lose the reading; please ensure the results have been downloaded to GastroCHART™ or have been recorded manually.*

Remove the mouthpiece and sample line between tests to purge sensors with fresh air.

Maintenance

Routine maintenance

WARNING: Do not open the GastroCH$_4$ECK® Gastrolyzer®, this could result in bodily harm.

NOTE: *Servicing should only be carried out by a Bedfont® trained representative.*

1. Mouthpieces should be replaced after every patient.
2. Hands should be washed regularly in accordance with infection control practice.
   CAUTION: Do not use hand sanitising products containing alcohol as this may damage the sensors.
3. The GastroCH$_4$ECK® should be switched off once every 24 hours.
4. Only use accessories approved by Bedfont®.
   CAUTION: Please do not attempt to modify the device in any way or use accessories not specified by the manufacturer. Any attempt to do so, will invalidate the warranty and may cause product failure or damage to your GastroCH$_4$ECK® Gastrolyzer® device. The product warranty does not cover product failure or damage resulting from use with non-approved accessories.
5. The device must be calibrated once every 4 weeks. See the 'Calibration' section of this manual for instructions.
6. The device will provide daily reminders via the reminder screen after turning on the GastroCH$_4$ECK® Gastrolyzer® for 1 month leading up to the sensor change due date. Once this date has elapsed the date will turn red to indicate that sensor replacement is overdue:
   a. The H_2 sensor should be replaced every 2 years.
   b. The O_2 sensor should be replaced every 2 years.
   c. The CH_4 sensor should be replaced every 5 years.

   CAUTION: Sensor use beyond the specified component lifetime without servicing may compromise result accuracy.
   NOTE: *Bedfont® recommends an annual service in order to check sensor and component parts performance.*

Cleaning

Bedfont® recommends wiping the device external surfaces with a product specifically developed for this purpose. An EPA registered alcohol free disinfectant should be used, such as Sani-Cloth AF3 Germicidal Disposable Wipe. Cleaning should be performed following the instructions for use specified by the manufacturer of the EPA registered disinfectant. The device or consumables cannot be sterilized. It is recommended that wipes are used once and for one surface only. The GastroCH$_4$ECK® Gastrolyzer® device should be cleaned for initial use and after each patient use.

WARNING: Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the electrochemical sensor inside.

WARNING: Under no circumstances should the device be immersed or splashed with liquid.

Calibration

The GastroCH$_4$ECK® Gastrolyzer® should be calibrated every 4 weeks and will give a reminder during start-up when calibration is due. The calibration gas required is 100ppm H_2, 100ppm CH_4 and 20.9% O_2.

NOTE: *Please allow the GastroCH$_4$ECK® to be switched on for at least 5 minutes prior to calibration*

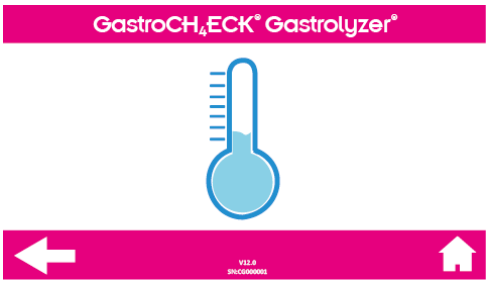
NOTE: *The GastroCH$_4$ECK® device temperature needs to be at 21°C ± 4°C (69°F ± 39°F) to be able to perform a calibration.*

Open the settings menu and start the calibration process by choosing the calibrate icon.

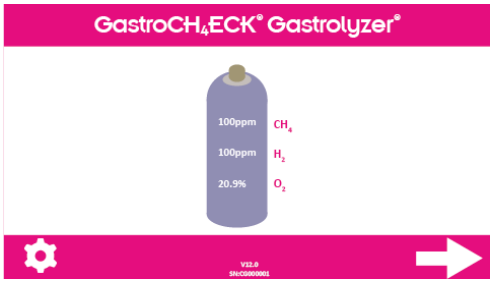
First the device must be zeroed and this will happen automatically.

NOTE: *Do not connect the gas at this stage.*

The temperature of the GastroCH$_4$ECK® is above 25°C (77°F) and is too hot to be calibrated. Please move the device to a cooler area and try again later.

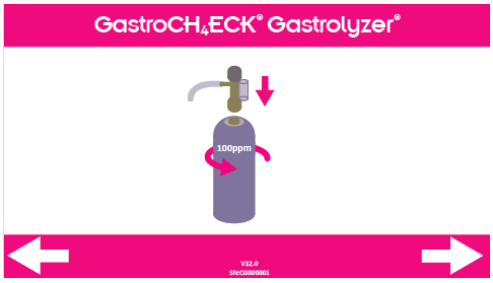


The temperature of the GastroCH$_4$ECK® is below 17°C (62°F) and is too cold to be calibrated. Please move the device to a warmer area and try again later.

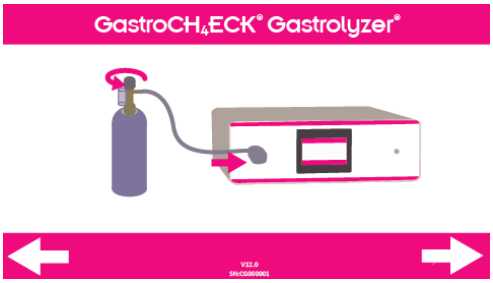


Once the zero is complete, follow the calibration process as shown onscreen.

Verify calibration gas is the correct gas concentration.



Screw the gas canister into the regulator.



Attach the CaliAdaptor to device via the sample line and open the gas canister. Press the arrow to begin the calibration.

NOTE: *Gas flow should be set to 1 litre per minute.*

A successful calibration will be indicated by the green tick; return to the home screen.

A failed calibration will be indicated by the red cross; press the retry icon to attempt calibration again. If the problem persists, see ‘Troubleshooting’. Alternatively, return to the home screen.

Technical Specification

			GastroCH$_4$ECK® Gastrolyzer®
Concentration range	**CH_4**		0-200 ppm
	H_2		0-200 ppm
	O_2		14-23%
Power input			230V/100V, 50Hz – 60 Hz, 0.5 – 1.0 A
Fuse			T 3.15 AH
Start-up time			≤2 minutes
Calibration frequency			Every 4 weeks
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°-95°F)
	Storage		0-40°C (32°-104°F)
Pressure range	**Operating**		912-1114mbar (Atmospheric ±10%)
	Storage		912-1114mbar (Atmospheric ±10%)
Humidity range	**Operating**		30-75% RH (non-condensing)
	Storage		15-90% RH (non-condensing)
Expected 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. 8.5kg
Device construction and Materials			Case: aluminium Mouthpiece: polypropylene Face Mask Sampling System: polypropylene, Styrenebutadieneplastic & silicone Face Masks: polyvinyl chloride and polyethylene
Classification and Regulatory Information			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	2 years*

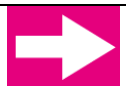
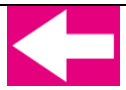
*Subject to maintenance and service.

NOTE: *At 25°C (77°F) ambient temperature the expected lifetime of the device is at least 30,000 hrs. For every 10°C (50°F) rise in temperature, the lifetime is reduced by half.*

Using the GastroCH$_4$ECK® Gastrolyzer® with GastroCHART™

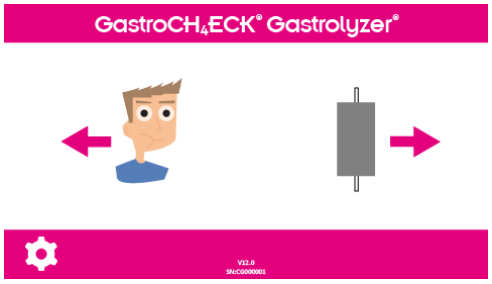
The GastroCH$_4$ECK® Gastrolyzer® can be used with the GastroCHART™ software, which is a free patient management software. GastroCHART™ software can be downloaded and installed from the USB that comes with the GastroCH$_4$ECK® Gastrolyzer®. Place one end of the USB cable into the USB port at the rear of the GastroCH$_4$ECK® and the other end to the USB port on the PC. Before starting the software, ensure that the GastroCH$_4$ECK® Gastrolyzer® is connected to the PC and switched on. Double click the GastroCHART™ icon on the PC to start the programme. Refer to the GastroCHART™ manual for instructions on how to use the software.

Buttons

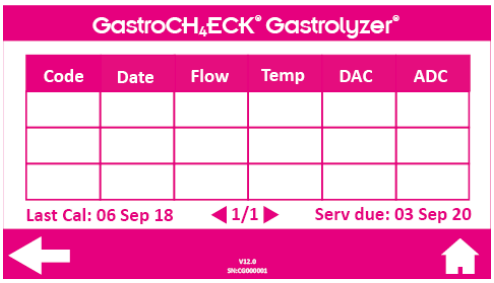
Breath test		Home	
Breath bag test		Settings	
Next step		Log	
Previous step		Calibration	
Test quality		Service area (PIN protected)	

Troubleshooting

When the GastroCH$_4$ECK® encounters an error, it will be recorded in the log for referrals when seeking troubleshooting assistance.

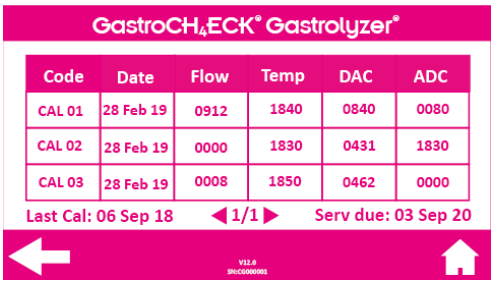


To access the log, go to the settings menu and then select the log icon.



NOTE: *All errors logged are not saved in the device's memory and therefore the log is reset every time the device is restarted*

Please refer to the following list to troubleshoot any error codes:



NOTE: *Calibration errors will only appear in the log and not as a separate warning. The possible errors are:*

- *CAL 01 = H_2 calibration fail*
- *CAL 02 = O_2 calibration fail*
- *CAL 03 = CH_4 calibration fail*

Calibration due – please refer to the ‘Calibration’ section of this manual.

Sensor change due in 30 days.

Sensor change overdue.

The device has been running for more than 16,000 hours.

H_2 sensor zero failure: Reattempt breath test or bag test. If failure persists contact Bedfont® or their distributor for support.

O_2 sensor zero failure: Reattempt breath test or bag test. If failure persists contact Bedfont® or their distributor for support.

CH_4 sensor sync error: Press the retry button. If the error occurs more than 3 times, please restart the device. If failure persists contact Bedfont® or their distributor for support.

CH_4 sensor connectivity error: Press the retry button. If the error occurs more than 3 times, please restart the device. If failure persists contact Bedfont® or their distributor for support.

CH_4 sensor check sum/end char error: Press the retry button. If the error occurs more than 3 times, please restart the device. If failure persists contact Bedfont® or their distributor for support.

CH_4 sensor error: Check that the ambient temperature is within range and that the device is plugged correctly. Then press the retry button. If the error occurs more than 3 times, please restart the device. If failure persists contact Bedfont® or their distributor for support.

CH_4 sensor failure: Press the retry button. If the error occurs more than 3 times, please restart the device. If failure persists contact Bedfont® or their distributor for support.

CH_4 sensor reading error: Verify that no gas is flowing through the device. If gas was being used, please wait 5 minutes before attempting a new test and then press the retry button. If the error occurs more than 3 times, please restart the device. If failure persists contact Bedfont® or their distributor for support.

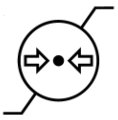
Calibration failed: Check calibration gas tubing is connected to the breath sampling port.

Reattempt calibration. If failure persists contact Bedfont® or their distributor for support.

Glossary of Symbols and Safety Information

Glossary of Symbols and Safety Information			
Title of Symbol	**Symbol**	**Explanatory Text**	**Symbol & Standard References**
Degree of protection against electric shock	N/A	Type BF applied part	N/A
Type of protection against electric shock	N/A	Class I equipment; (earthed)	N/A
Degree of safety application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	N/A	Equipment not suitable for use in the presence of flammable mixtures	N/A
Degree of protection against ingress of liquid	**IPX0** not protected against water ingress	Degree of Ingress Protection Provided by Enclosure	IEC 60601-1, Table D.3, Symbol 2 IEC 60529
Alternating Current		Alternating Current	IEC 60601-1, Table D.1, Symbol 1 ISO 7000/IEC 60417-5032
Caution		To indicate that caution is necessary when operating the device or control close to where the symbol is placed. To indicate that the current situation needs operator awareness or operator	ISO 15223 – 1. Clause 5.4.4 ISO 7000 – 0434A

		action in order to avoid undesirable consequences	IEC 60601-1, Table D.1, Symbol 10
Consult instructions for use	 **www.bedfont.com**	Indicates the need for the user to consult the instructions for use. (**NOTE:** The eIFU indicator can be a manufacturer's website URL or some other appropriate indication that the instructions for use are available in an electronic format.)	ISO 15223 – 1. Clause 5.4.3 ISO 7000 – 1641 IEC 60601-1, Table D.1, Symbol 11
Serial Number		Indicates the manufacturers serial number so that a specific medical device can be identified	ISO 15223 – 1. Clause 5.1.7 ISO 7000 – 2498
Non-ionizing electromagnetic radiation		To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment	IEC 60601-1-2 Clause 5.1.1 IEC 60417 - 5140
Keep dry		Indicates a medical device that needs to be protected from moisture	ISO 15223 – 1, Clause 5.3.4 ISO 7000 – 0626
WEEE (Waste Electrical and Electronic Equipment)		DO NOT THROW IN GENERAL RUBBISH DISPOSAL/TRASH! – Waste Electronic Equipment	EN 50419 Directive 2012/19/EU, Annex IX
Date of Manufacture		Indicates the date when the medical device was manufactured	ISO 15223 – 1. Clause 5.1.3 ISO 7000 – 2497 FDA 21 CFR 801

Manufacture		Indicates the medical device manufacturer (*Note – Date of manufacture, name and address of manufacturer can be combined in one symbol	ISO 15223 – 1. Clause 5.1.1 ISO 7000 – 3082
Type BF Applied Part (Whole Device)		To identify a type BF applied part complying with IEC 60601-1 (Degree of protection against electric shock)	IEC 60417-5333 IEC 60601-1, Table D.1, Symbol 20
Temperature limit		Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.7 ISO 7000 – 0632
Humidity limitation		Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.8 ISO 7000 – 2620
Atmospheric pressure limitation		Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.9 ISO 7000 – 2621
Authorised representative in the European Community		Indicates the authorised representative in the European Community	ISO 15223 – 1. Clause 5.1.2
Unique device identifier		Indicates a carrier that contains unique device identifier information	ISO 15223 – 1. Clause 5.7.10
Medical Device		Indicates the item is a medical device	ISO 15223 – 1. Clause 5.7.7
Catalogue number		Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223 – 1. Clause 5.1.6 ISO 7000-2493
CE mark		Manufacturer's declaration of compliance to all relevant European Medical Device Regulations	European Directive 93/42/EEC
Bedfont® logo		Manufacturers logo	n/a

Do not stack		To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.	ISO 7000-2402
General symbol for recovery/recyclable		To indicate that the marked item or its material is part of a recovery or recycling process.	ISO 7000-1135
Fragile, handle with care		Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 15223-1 Clause 5.3.1 ISO 7000-0621

Environment

Electromagnetic Immunity

The GastroCH$_4$ECK® Gastrolyzer® complies with the directive IEC/EN 60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding the levels specified in IEC/EN 61000-4.

Guidance and manufacturer's declaration: Electromagnetic Immunity (IEC 60601-1-2)			
The GastroCH$_4$ECK® Gastrolyzer® is intended for the use in the electromagnetic environment specified below. The customer or the user of the GastroCH$_4$ECK® Gastrolyzer® should assure that it is used in such an environment.			
Test Type	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated Emissions: EN55011:2016 + A1:2017 FCC Part 15 Subpart B	30MHz to 1GHz	Met or exceeded	
Conducted Emissions: EN55011:2016 + A1:2017 FCC Part 15 Subpart B	150kHz to 30MHz	Met or exceeded	
Conducted Emissions (Discontinuous Disturbance): EN55011:2016 + A1:2017 (EN55014-1)	150kHz to 30MHz	Met or exceeded	
Radiated Immunity: EN61000-4-3:2006 IEC61000-4-3:2006/AMD2:2007	3V/m (1kHz 80%) 80MHz – 2.7GHz 385 MHz 27 V/m PM 18 Hz 450 MHz 28 V/m FM 1 kHz sine 710 MHz 9 V/m PM 217 Hz 745 MHz 9 V/m PM 217 Hz 780 MHz 9 V/m PM 217 Hz 810 MHz 28 V/m PM 18 Hz 870 MHz 28 V/m PM 18 Hz 930 MHz 28 V/m PM 18 Hz 1720MHz 28 V/m PM 217 Hz 1845 MHz 28 V/m PM 217 Hz 1970 MHz 28 V/m PM 217 Hz 450 MHz 28 V/m PM 217 Hz 5240 MHz 9 V/m PM 217 Hz 5500 MHz 9 V/m PM 217 Hz 5785 MHz 9 V/m PM 217 Hz	Met or exceeded	Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted Immunity: EN61000-4-6:2014 (UD) IEC61000-4-6:2015 (UD)	3V rms(1kHz 80%) 150kHz – 80MHz 6V rms ISM and amateur radio bands	Met or exceeded	Portable and mobile RF communications equipment should be used no closer to any part of the GastroCH$_4$ECK® Gastrolyzer® including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.

Voltage Dips and Interrupts: EN61000-4-11:2004 IEC61000-4-11:2005	240VAC 500ms (50Hz/60Hz) 70% @ 0° 240VAC 20ms (50Hz/60Hz) 100% @ 0° 240VAC 10ms (50Hz/60Hz) 100% @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 240VAC 5s (50Hz/60Hz) 100% 100VAC 500ms (50Hz/60Hz) 70% @ 0° 100VAC 20ms (50Hz/60Hz) 100% @ 0° 100VAC 10ms (50Hz/60Hz) 100% @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100VAC 5s (50Hz/60Hz) 100%	Met or exceeded	
Power Frequency Magnetic Field: EN61000-4-8:2010 IEC61000-4-8:2012	30 A/m magnetically sensitive equipment	Met or exceeded	
Fast Transient Burst: EN61000-4-4:2012 IEC61000-4-4:2016	± 2kV	Met or exceeded	
Surge: EN61000-4-5:2006 IEC 61000-4-5:2008 Consolidated version	± 0.5, 1.0 kV L-L ± 0.5, 1.0, 2.0 kV L-E 20 s	Met or exceeded	
ESD: EN61000-4-2:2009 IEC 61000-4-2:2012	± 8kV contact ±, 4,8,15kV air	Met or exceeded	

The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GastroCH$_4$ECK® Gastrolyzer® is used exceeds the applicable RF compliance level above, the GastroCH$_4$ECK® Gastrolyzer® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GastroCH$_4$ECK® Gastrolyzer®.

Electrical Safety

WARNING: To reduce the risk of electrical shock, this device uses a three-wire electrical cord and plug to connect the GastroCH$_4$ECK® Gastrolyzer® to earth-ground.

To preserve this safety feature:

• Make sure that the matching wall outlet receptacle is properly wired and earth-grounded. Check that the line voltage agrees with the voltage listed on the rear label affixed to the GastroCH$_4$ECK® Gastrolyzer®.

• Do not install the GastroCH$_4$ECK® Gastrolyzer® on a ground fault-protected power source.

• Do not place containers holding liquid on or near the GastroCH$_4$ECK®. If they spill, liquid may enter the GastroCH$_4$ECK® Gastrolyzer® and damage electrical or mechanical components.

• Only use properly rated safety fuses as described on the rear of the GastroCH$_4$ECK® (T 3.15 AH 250V).

Safety against risk of fire

WARNING: Fuses protect certain electrical circuits within the GastroCH$_4$ECK® Gastrolyzer® against overcurrent conditions.

WARNING: For continued protection against the risk of fire, replace only with the same type and rating specified.

WARNING: Only fuses with the following ratings should be applied: 250Vac, 3.15AH T, 1500A breaking capacity.

WARNING: The GastroCH$_4$ECK® Gastrolyzer® is not designed for use with materials capable of developing flammable or explosive vapours.

Mechanical safety

For safe operation of the equipment, observe the following:

CAUTION: Use only accessories designed for use with the GastroCH$_4$ECK® Gastrolyzer®.

WARNING: If the GastroCH$_4$ECK® Gastrolyzer® is used in a manner other than that specified in this manual, the safety and performance of this equipment could be impaired. Further, the use of any equipment other than that recommended by Bedfont® has not been evaluated for safety. Use of any equipment not specifically recommended in this manual is the sole responsibility of the user.

Warranty

Bedfont® Scientific Limited warrants the GastroCH_4ECK® Gastrolyzer® product to be free of defects in materials and workmanship for a period of 2 years from the date of shipment, subject to maintenance and service.

Bedfont's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned, intact and prepaid, to Bedfont® Scientific Limited or the local representative.

This warranty is automatically invalidated if the products are altered or tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident. At the end of the product's life, contact Bedfont® or its distributor for disposal instructions.

Single use consumables and accessories should be disposed of in line with local clinical waste guidelines.

Never dispose of any electronic instrument or batteries in domestic waste. At the end of the product's life, contact Bedfont® or its distributor for disposal instructions.

Returns

Please contact Bedfont® or their local distributor for instructions on returning goods.

Responsible Manufacturer and Contacts

Bedfont® Scientific Ltd.
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Maidstone, Kent,
ME17 1JA
United Kingdom

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