covita™
breath analysis is the new blood test

bedfont

GastroCH$_4$ECK™

Operating Manual

V.11.0 Firmware

breath analysis is the new blood test

www.covita.net | (800) 707-5751

Contents

Introduction

Read all product manuals and consult with Bedfont-trained personnel before attempting to operate the GastroCH$_4$ECK Gastrolyzer. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Bedfont representative.

Safety operation Notes

To avoid electric shock, this equipment must be connected to a mains supply with protective earth.

The operator should not touch the patient whilst in contact with either the computer or the USB connector parts.

The GastroCH$_4$ECK Gastrolyzer should only be connected to a computer that is manufactured in accordance with EN60950 – Safety of information technology equipment.

Please do not attempt to modify the equipment in any way or use accessories not specified for use by the manufacturer. Any attempt to do so will invalidate the warranty and may affect the safety of the device.

The monitor is not suitable for use in an oxygen rich environment.

WARNING

No modification of this equipment is allowed.

Any modification to this equipment during the actual service life requires evaluation to the requirement of EN 60601-1:2006

Contraindications

If exhaling gently as per the instructions is physically demanding, it is contrindicated in patients with recent myocardial infarction. Also extensive exhalaton might lead to syncope.

Safety During installation and/or Maintenance

This GastroCH$_4$ECK Gastrolyzer can be installed by a trained user as long as the instruction manual has been read.

This GastroCH$_4$ECK Gastrolyzer weighs 6kg.

Any servicing of this equipment that requires removal of any covers can expose parts which involve the risk of electric shock or personal injury. Do not open the GastroCH$_4$ECK Gastrolyzer. This could result in a void in warranty. This should be carried out by a Bedfont trained representative.

Electrical Safety

To reduce the risk of electrical shock, this equipment 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.

Safety Against Risk of Fire

Fuses protect certain electrical circuits within this GastroCH$_4$ECK Gastrolyzer against overcurrent conditions. For continued protection against the risk of fire, replace only with the same type and rating specified.

This GastroCH$_4$ECK Gastrolyzer is not designed for use with materials capable of developing flammable or explosive vapors. Do not use such materials (such as chloroform or ethyl alcohol) in this GastroCH$_4$ECK Gastrolyzer nor handle or store them within the required 30-cm (1-ft) area surrounding the GastroCH$_4$ECK Gastrolyzer.

Mechanical Safety

For safe operation of the equipment, observe the following:

- Use only accessories designed for use in this GastroCH$_4$ECK Gastrolyzer.
- Do not lift or move the GastroCH$_4$ECK Gastrolyzer while it is running.This could damage the Methane Bench.

Environment

The GastroCH$_4$ECK complies with the directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding the levels specified in EN50082:1

Guidance and manufacturer's declaration: Electromagnetic Immunity (IEC 60601-1-2)			
The GastroCH$_4$ECK™ is intended for the use in the electromagnetic environment specified below. The customer or the user of the GastroCH$_4$ECK™ should assure that it isused in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/ or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to neutral ±2 kV line to earth	Mains power quality should be that of a typical commercial and/ or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (95 % dip in U_T) for 5 s.	100% dip for 5s	Mains power quality should be that of a typical commercial and/ or hospital environment. If the user of the GastroCH$_4$ECK requires continued operation during power mains interruption, it is recommended that the GastroCH$_4$ECK be powered from an uninterruptible power supply or battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration: Electromagnetic Immunity (IEC 60601-1-2)			
The GastroCH$_4$ECK™ is intended for the use in the electromagnetic environment specified below. The customer or the user of the GastroCH$_4$ECK™ should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz ~ 80MHz outside ISM bands* 10 V rms 150 kHz ~ 80MHz in ISM bands* 10 V rms 80 kHz ~ 2.5 GHz	3 V rms 3 V/m 80MHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the GastroCH$_4$ECK including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with he following symbol: 

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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 is used exceeds the applicable RF compliance level above, the GastroCH$_4$ECK 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.

Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 3 V/m.

Caution

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.

Caution

Degree of safety of application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide: Equipment not suitable for use in the presence of flammable mixtures.

Recycling Label

This symbol is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

- The device was put on the European market after August 13, 2005 and the device is not to be disposed of via the municipal waste collection system of any member state of the European Union. It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment. For Bedfont products bearing this label, please contact your dealer for details of how to undertake the proper collection, treatment, recovery, recycling, and safe disposal of the device.

Explanation of symbols on instrument

	Alternating current
	Direct Current
Degree of protection against electric shock:	
	Type BF applied part
Degree of safety of application in the prescence of a flammable anaesthetic mixture with air oxygen or nitrous oxide: Equipment not suitable for use in the presence of flammable mixtures.	
Type of protection against electric shock: Class I equipment; (earthed)	
Caution	Please refer to the warnings and safety notes in this manual
Degree of protection against ingress of liquid: IPXO - not protected against water ingress	
	Consult instructions for use

Caution

CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).

Important

IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the Important adds benefit to the performance of a piece of equipment or to a process.

Note

NOTE is used to call attention to notable information that should be followed during installation, use, or servicing of this equipment

Chapter 1 - Scope of the Manual

This manual is designed to acquaint you with the GastroCH$_4$ECK Gastrolyzer, its functions, specifications, operation, and routine operator care and maintenance. We recommend that you read this entire manual, especially the SAFETY NOTICE and all safety-related information, before operating the GastroCH$_4$ECK Gastrolyzer or performing any maintenance.

- Chapter 1 contains a brief overview of the manuals and descriptions for each chapter.
- Chapter 2 outlines the requirements for installation of the GastroCH$_4$ECK
- Chapter 3 contains a brief description of the GastroCH$_4$ECK.
- Chapter 4 contains the definition of intended use of the device.
- Chapter 5 contains an introduction to the relevance of Methane and Hydrogen testing.
- Chapter 6 contains the technical information for the device.
- Chapter 7 contains information necessary to be able to operate the device.
- Chapter 8 has the breath bag sample collection procedure.
- Chapter 9 has all the information required for maintenance of the device
- Chapter 10 outlines the procedure for returning the instrument to Bedfont for service or warranty issues.
- Chapter 11 all spare parts information.
- Chapter 12 contains warranty information.

Caution

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.

Caution

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with nitrous oxide

Chapter 2 - Installation Requirements

Installation requirements have been provided for your GastroCH4ECK Gastrolyzer. Refer to this information when installing your GastroCH4ECK for the first time and when moving the equipment to a new location.

Contact Bedfont technical department at tech@bedfont.com if you require further information.On first install the device should be left for 24 hours before use.

Space Requirements

WARNING

Do not place the GastroCH4ECK Gastrolyzer near areas containing flammable reagents or combustible fluids. Vapors from these materials could enter the GastroCH4ECK Gastrolyzer air system and be ignited.

Maintain a 30-cm (1-ft) clearance envelope above the GastroCH4ECK Gastrolyzer while it is running.

The equipment should not be positioned such that it is difficult to operate the disconnection device (Mains Plug).

If it is necessary to move the GastroCH4ECK Gastrolyzer, maintain the following conditions:

1. Select a location away from heat-producing laboratory equipment, with sufficient ventilation to allow heat dissipation.
2. Position the GastroCH4ECK Gastrolyzer on a level surface, such as a sturdy table or laboratory bench that can support the weight of the GastroCH4ECK Gastrolyzer 6 kg and resist vibration. Place the GastroCH4ECK Gastrolyzer at least 5 cm (2 in.) from the front edge of the laboratory bench.
3. In addition to space for the GastroCH4ECK Gastrolyzer, allow 15.2 cm (6-in.) clearances at the sides and back to ensure sufficient air circulation. The GastroCH4ECK Gastrolyzer must have adequate air ventilation to ensure compliance to local requirements for vapors produced during operation.
4. Relative humidity should not exceed 75% (non condensing)

Temperature Requirements

Temperature should not exceed those stated in the specifications section of the document.

The monitor should be calibrated at the same temperature at which it would be used. Therefore the unit cannot be used before the warm-up period has elapsed. If the unit is accidently switched off or needs to be moved. Depressing the Start/ Stop button for 3 seconds will bypass the warm-up countdown. However this must only be done within 2 minutes of the unit being switched off, as using the device without the correct warm-up time will compromise accuracy.

NOTE

The instrument should be calibrated prior to first use and after transportation.

Electrical Requirements

WARNING

To avoid the risk of electrical shock, this equipment must only be connected to a supply with protective earth.

To reduce the risk of electrical shock, this GastroCH$_4$ECK Gastrolyzer uses a 2-m (6-ft) three-wire electrical cord to be attached to the AC power connector at the rear of the GastroCH$_4$ECK Gastrolyzer and a plug to connect to earth-ground. (A plug that meets your local electrical and safety requirements was supplied with the GastroCH$_4$ECK Gastrolyzer. Contact your local distributor for specific information regarding local requirements.)

To preserve this safety feature:

- Make sure that the matching wall outlet receptacle is properly wired and earth-grounded. Verify that the line voltage agrees with the voltage listed on the rear label affixed to the GastroCH$_4$ECK Gastrolyzer. Then plug in the power cable to the instrument and the wall outlet.
- Never use a three-to-two wire plug adapter.
- Never use a two-wire extension cord or a two-wire non-grounding type of multiple-outlet receptacle strip.
- In case of a malfunction, the GastroCH$_4$ECK Gastrolyzer can be disconnected from the main power source

NOTE

The equipment operation can be safely terminated at any time by switching the power switch to the off position.

PC Connectivity Requirements

NOTE

When you connect other equipment to the GastroCH$_4$ECK unit, always make sure that the whole combination complies with the collateral standard IEC 60601-1: 2005 / EN 60601: 2006 Clause 16. Safety requirements for medical electrical systems.

Such parts should not be accessible to the patient and the operator should be instructed not to touch the equipment, the USB , the computer and the patient at the same time. The use of an IEC 60601-1: 2005 / EN 60601: 2006 compliant computer or a separating transformer is recommended.

Chapter 3 - Brief Description

The GastroCH$_4$ECK is a portable Gastrolyzer monitor that measures Hydrogen (H_2), Methane (CH_4) and Oxygen (O_2) for the purpose of aiding the diagnosis of some gastrointestinal conditions.

The GastroCH$_4$ECK design features a real-time patient breath analysis function, bag sample analysis, oxygen correction of contaminated samples, active temperature compensation, self purging sequence and synchronization with a PC loaded with the GastroCHART software.

Real Time Patient Breath Analysis

The GastroCH$_4$ECK has the capability for patients to exhale directly into the device and their breath samples will be analyzed in real time and results displayed after exhalation.

Real time measurement of the oxygen contents of breath samples encourages patients to achieve end-tidal breath tests.

Single patient use mouthpieces are provided for this purpose for cross-infection control.

Bag Sample Analysis

Breath bag samples collected remotely can also be analysed with the GastroCH$_4$ECK.

This allows the consultant to conduct a study on large groups of patients.

Single patient use breath bags are provided for this purpose.

Oxygen Correction

The GastroCH$_4$ECK measures the Oxygen data to correct for errors that could have arisen from either patients not achieving end-tidal breath sample collection or samples that have been contaminated from atmospheric air. End tidal breath requires an oxygen level of less than 13.9%. Therefore, if the breath sample contains more oxygen than this the GastroCH$_4$ECK will automatically correct the reading, giving an accurate result. However the ‘Limit Line’ will turn green at 15% O_2 as at this level the correction is very small but may be more comfortable for the patient to perform.

NOTE

It is desireable that reasonable steps are taken to ensure that patients achieve end tidal breath sampling during collection and also that sample contamination is avoided.

Following the steps outlined on page 22 *Chapter 8: Breath Bag Sample Collection Procedure* will assist in this.

PC Connectivity

The GastroCH$_4$ECK can be connected to a desktop computer or laptop computer for real time acquisition of patient test data. Using the GastroCHART software, graphs can be generated to show the patient response to administered test substrate.

Chapter 4 - Intended Use

The GastroCH$_4$ECK is a portable desktop monitor which measures both Hydrogen (H_2) and Methane (CH_4) levels in expired breath samples in response to appropriate substrates. The GastroCH$_4$ECK also measures O_2 to ensure accurate results from errors that could have arisen from either patients not achieving end-tidal breath sample collection, or samples that have been contaminated from atmospheric air.

The expired breath can be delivered direct to the monitor for immediate analysis or via a sample taken remotely via breath-bag for subsequent analysis.

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

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

Specific diagnosis is not possible with this device; further specific testing would need to be carried out to diagnose a patient's condition.

This monitor is intended for multi-patient use on children and adults by healthcare professionals in a clinical environment as well as a home setting in which the sample is gathered in the bag and sent to the clinic for analysis.

Chapter 5 - Introduction

Hydrogen (H_2) and Methane (CH_4) are generated in the intestinal lumen by bacterial action on carbohydrates in the large or small intestine.

Once the resultant H_2 and CH_4 are diffused into the bloodstream and then to the alveoli, it can be detected in expiratory air. There exists a correlation between intestinal lumen H_2 and CH_4 production and H_2 and CH_4 excretion in expiratory air.

Accurate measurement of H_2 and CH_4 in parts per million (ppm) in expiratory air reveals abnormal breakdown and/or malabsorption of carbohydrates.

The GastroCH$_4$ECK is a simple to operate device with options for both real time breath test and a bag sample test which allows patient breath to be collected in breath bags and analyzed on the device.

It also implements a normalizing factor for correcting errors in readings that could have occurred from sample contamination or incorrect breath sample collection.

It incorporates single patient use mouthpieces and breath bags for cross contamination control.

The GastroCH$_4$ECK can be used to indicate the following disorders:

- Carbohydrate breakdown deficiency
- Carbohydrate malabsorption
- Lactose intolerance
- Bacterial overgrowth
- Determination of time passage through the gut

Chapter 6 - Technical Description

NOTE

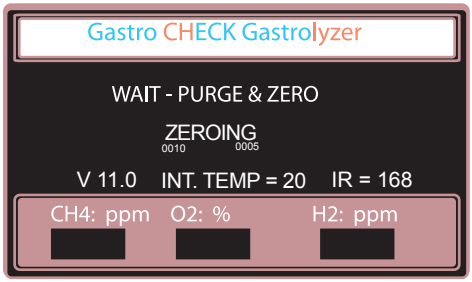
Bedfont will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of the equipment which are designated by the manufacturer as repairable, following service training.

The mains plug is used as the disconnect device.

The software version number is displayed at the bottom left corner of the display while it is in the zeroing mode.

The IR value which indicates the intensity of the light source of the methane sensor is also displayed on the bottom right corner of the display. The manufacturer should be contacted at tech@bedfont.com if this value drops below 60.

The INT. TEMP value relates to the operating temperature of the device and is used for fault finding.



Specification

Power Input:	230V/50Hz/100mA [115V/60Hz/220mA compatible]
Fuses:	T 160mAH 250V x2 (For 230V Version) T 315mAH 250V x2 (For 115V Versions)
Warm-up time:	30 minutes
Calibration frequency:	Once a month
Gases measured:	CH_4 H_2 O_2
Detection Principle:	H_2 and O_2 Electrochemical Sensor CH_4 Optical sensor
Measurement Range:	CH_4 0 – 200 ppm H_2 0 – 200 ppm O_2 0 – 100%
Accuracy:	
CH_4	Resolution: 1 ppm Accuracy: +/-(10% of reading)[1]
H_2	Resolution: 1 ppm Accuracy: ± 10%[2]
O_2	Resolution: 0.1% Accuracy: +/-2% full scale
Temperature Range:	Operational: 15 – 35 degrees C
Storage:	0 - 40 degrees C
Humidity Range:	Operational: 30 - 75 % non-condensing
Storage:	15 - 90% non-condensing
Pressure Range:	Operational: 900-1100 mBar
Transport / Storage:	800-1200 mBar
Dimensions:	300 x 265 x 140 mm
Weight:	Approx. 6kg
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
Applied Parts:	Dessicant Filter Sampling Line

[1]Conditions during factory calibration, typically 20°C, 1,000 mBar

[2]As per Chapter 2 Temperature Requirements

Chapter 7 - Operating Instructions

WARNING

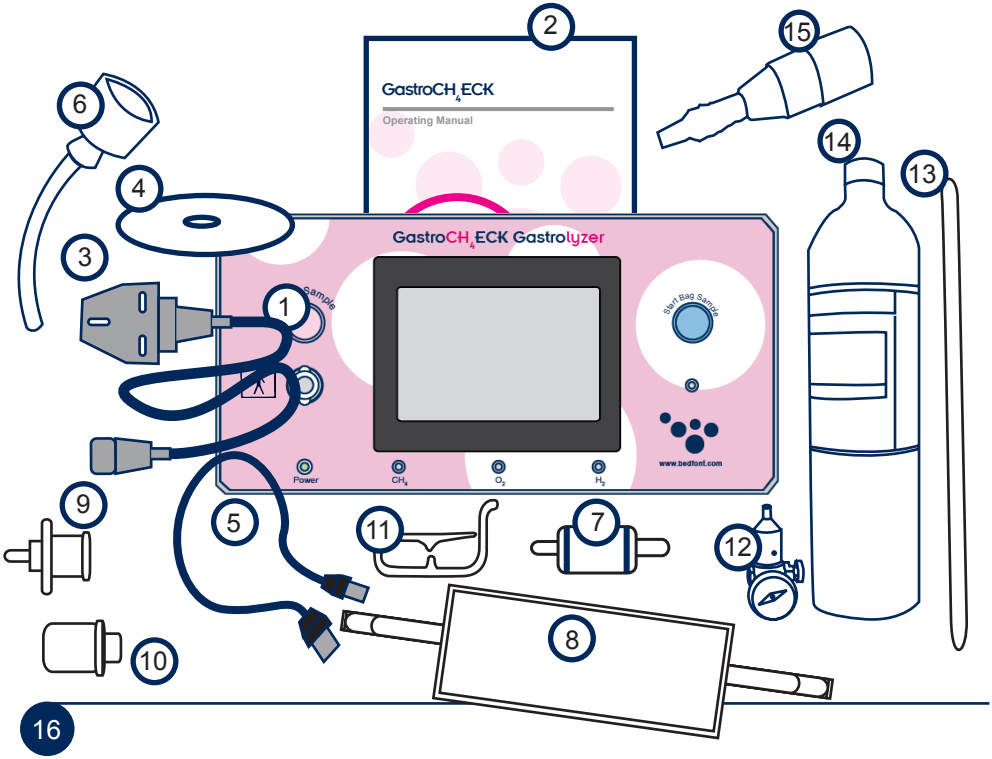
- When cleaning the monitor, never use alcohol, cleaning agents containing alcohol, or other organic solvents, as these vapours will damage the sensors inside the device.
- Under no circumstances should the Instrument be immersed in or splashed with liquid.
- Under no circumstances should the device be subjected to extreme force or dropped.
- The device cannot diagnose a specific condition; only indicate a possible range of conditions.
- The disposable mouthpieces are for single-patient use only. Multi-patient use will increase the risk of cross-infection.
- The disposable breath bags are for single-patient use only. Multi-patient use will increase the risk of cross-infection.
- Do not cover the exhaust port as this may affect the accuracy of the test.
- The GastroCH4ECK must be switched on in ambient air to ensure an accurate acclimatisation.
- The patient online breath mouthpieces (item number 10 in the pack content list) are provided for exhalation through the sampling line. Do not inhale through from/through the mouthpiece. Inhalation through the mouthpiece poses certain risks.
- The patient online breath mouthpieces are single patient use and should only be used for a maximum of 10 breath tests.
- Administered test substrate must be authorised by a qualified healthcare professional
- Consumables not specified by Bedfont must not be used with the device. Bedfont cannot guarantee the performance of the device if used with non-specified parts.
- No modification of this equipment is allowed.

Pack Contents List

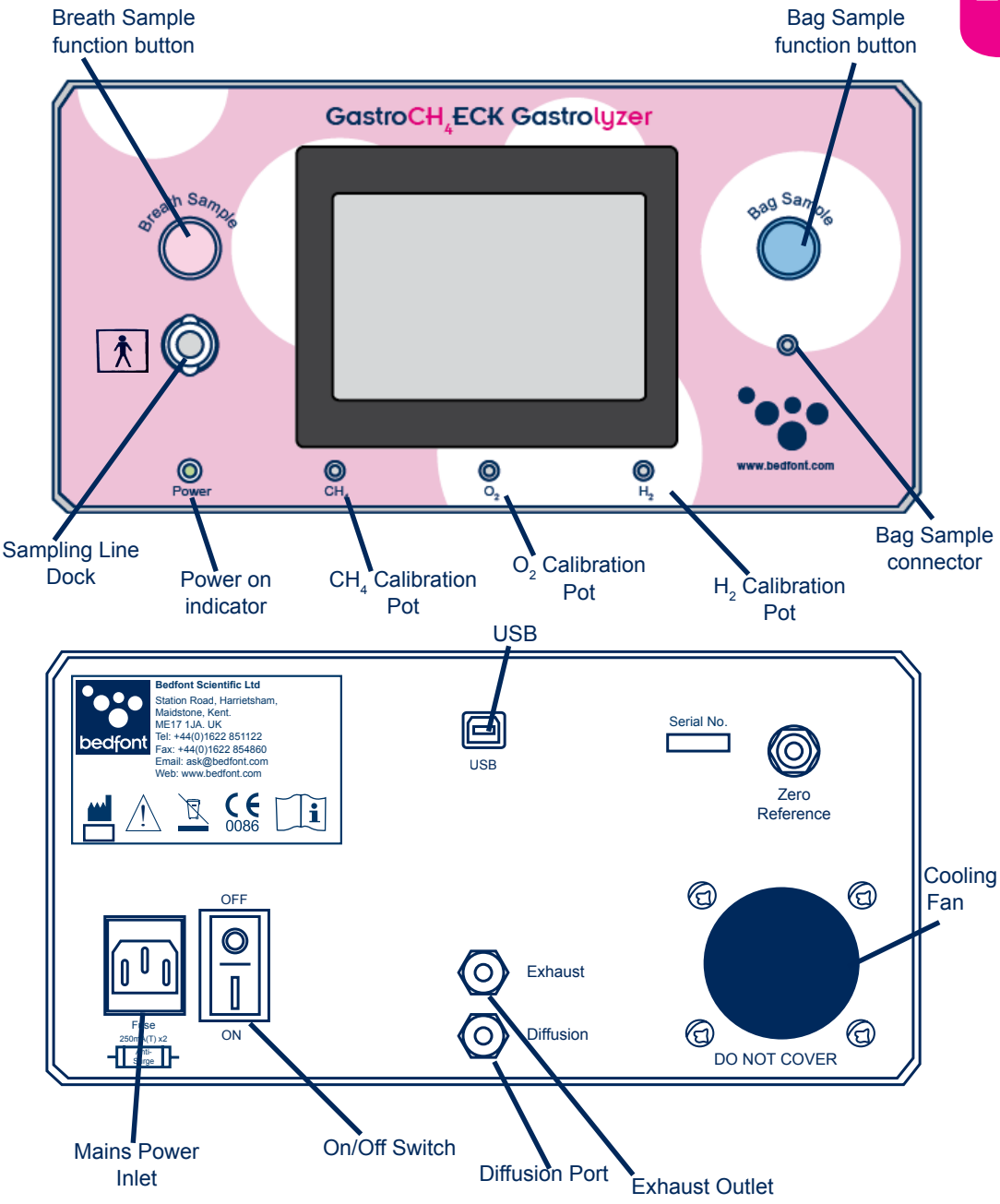
1. GastroCH4ECK Monitor
2. Operating Manual
3. Mains Cable
4. GastroCHART software
5. USB cable
6. Sampling line
7. Desiccant Filter
8. Breath Bag
9. Breath Bag Mouthpieces
10. Patient Online Breath Mouthpieces
11. Bag Clamp

Calibration Kit Content List

12. Regulator
13. Calibration Tubing
14. Combination Gas Canister
15. Calibration adaptor

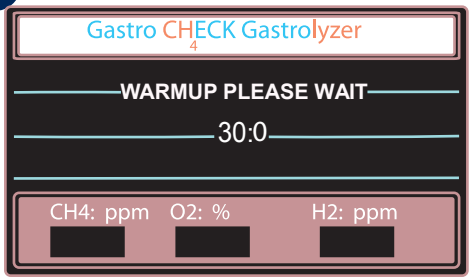


Instrument Layout

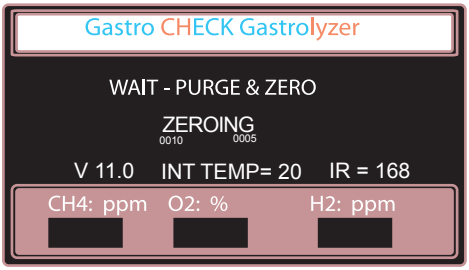


Display Symbols

Screen at startup

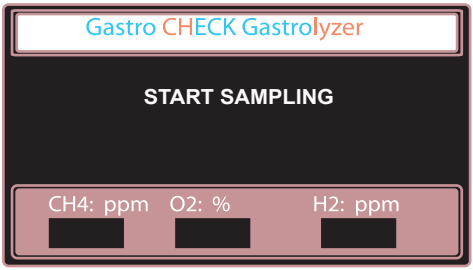


Screen when zeroing / purging

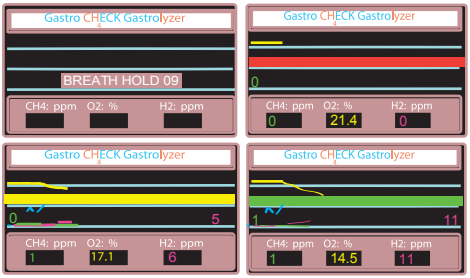


Key:
- CH_4
- O_2
- H_2
- Flow Rate

Screen when idle



Screen when test is running

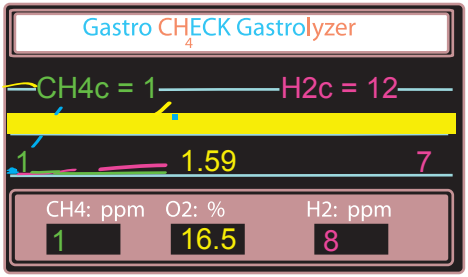


Screen when test result is displayed

CH4c = corrected CH_4

H2c = Corrected H_2

1.14 = Correction Factor



Setting up the GastroCH4ECK

1. Connect the power lead to the GastroCH4ECK via the socket on the rear of the panel (please see instrument layout). Connect to the electricity supply. (fig. 1)

2. Switch the monitor on using the on/off switch on the back of the unit. The green LED should light up. The GastroCH4ECK monitor will begin a purging process and the LCD should display a start up screen. (Fig. 2)

3. Connect the sampling line to the sample line dock for Breath samples. (Fig. 3)

4. Push desiccant filter onto bag sampling port for breath bag sampling. (Fig. 4)

5. Follow the instructions in the quick start guide to perform a sample analysis or Calibration as necessary.

Interpretation of 'Limit Line'

In order to motivate patients to perform a good End-tidal breath sample. The Gastrocheck displays a limit line on the screen. Denoting flow rate and oxygen concentration. The blue flow rate tracer should reach and be held in the limit line throughout the sample. The limit line will change from RED (denoting a bad sample) to YELLOW (denoting an acceptable sample) to GREEN (denoting a good sample.

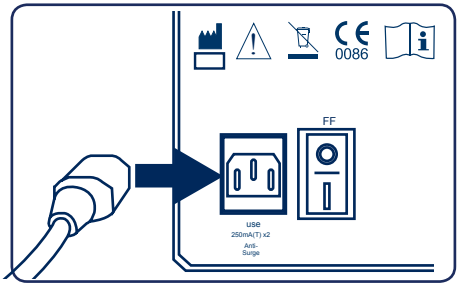


fig. 1

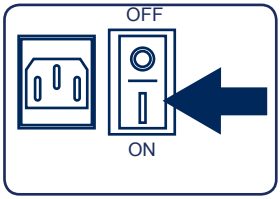


fig. 2

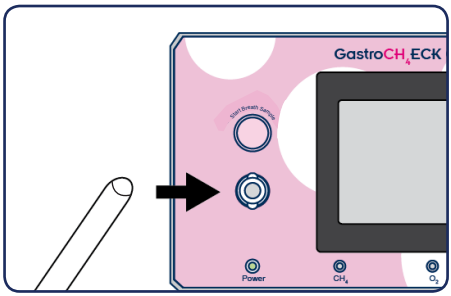


fig. 3

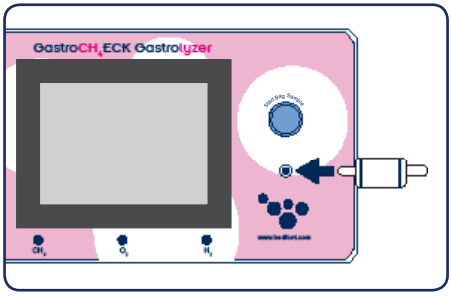


fig. 4

Quick Start Guide

Direct mode

1. Press the On/Off button at the back of the unit. The display will become active. (fig.5)
2. Leave the monitor to warm up for 30 minutes.
3. To perform a real time breath test, attach the sampling line into the docking port on the monitor, and push the mouthpiece into the soft silicone adapter on the sampling line. (fig. 7)
4. Press the “Breath Sample” button on the instrument to initiate a breath test. (fig. 8)
5. The monitor will commence a purge and zero routine. This should take approximately 1-2 minutes. On completion of the zero routine, the monitor will issue a beep sound which indicates for the patient to inhale and hold their breath. The screen will then show a 15 second countdown. (fig. 9)
6. When the countdown reaches zero exhale gently into the mouthpiece ensuring that you keep your breath flow up to the limit line.
7. When the limit line changes to green, PUSH the ‘breath sample’ button to finish the test.
8. The monitor will display real time values of the patient’s breath hydrogen and Methane as well as the oxygen value. The monitor will also display the peak values as well as the compensated values. (fig. 10)
9. Make a note of these values manually or automatically using GastroCHART™ and push the “breath sample” button to return to the home “Dormant” screen. (fig. 11 overleaf)

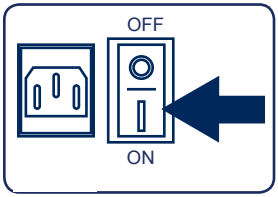


fig.5

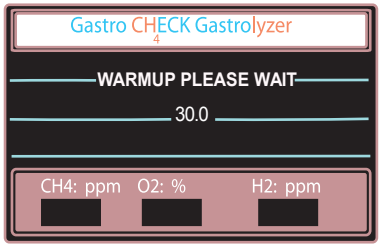


fig.6

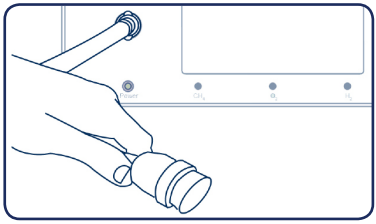


fig.7

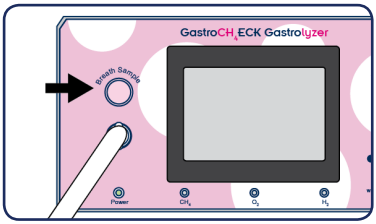


fig.8

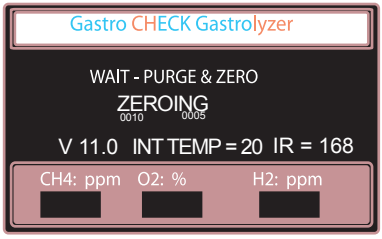


fig.9

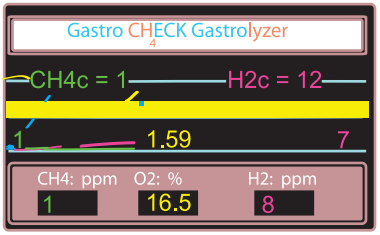


fig.10

Bag mode

1. Follow steps 1 and 2 from the Direct Mode of the Quick Start Guide.
2. To perform a bag sample measurement, attach the filled breath bag to the bag sampling inlet provided, via the available end of the desiccant filter (fig. 12)
3. Release the clamp from the tube end of the bag connected to the monitor.
4. Push the “Bag sample” button (fig. 13)
5. The monitor will commence a zero and purge sequence and will issue a beep sound when the sequence is completed. (fig. 14)
6. The monitor will draw samples from the bag at a set flow rate and will display the results after completion of the analysis. This should take approximately 45 seconds.
7. Both the peak and the compensated values will be displayed on the monitor on completion of analysis. The real time data will be displayed as the gas sample is being analyzed. (fig. 15)
8. IMPORTANT remove the breath bag before pressing the “Bag Sample” button to return to the home screen.

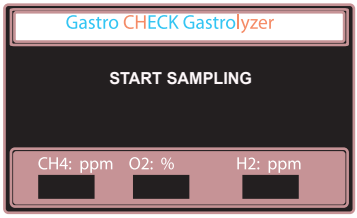


fig.11

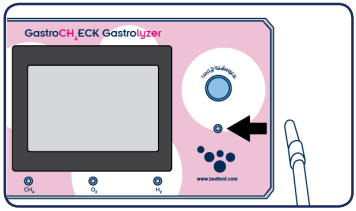


fig.12

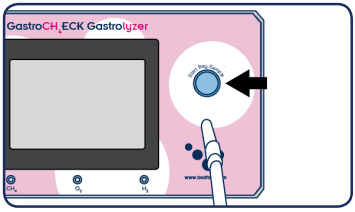


fig.13

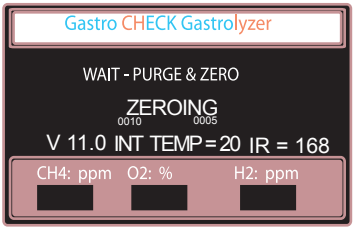


fig.14

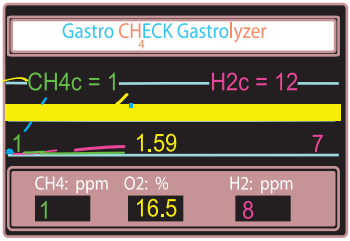


fig.15

PC Software Connection

1. To use the GastroCHART software, start the software using the icon on the PC
2. Connect a USB cable from the USB port on the instrument to an available USB port on the PC. (fig. 16)
3. Follow software instructions on saving patient profiles and saving data. Etc.
4. Software instructions can be found in the help section of the software.

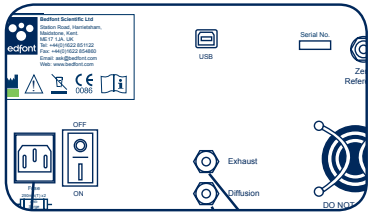


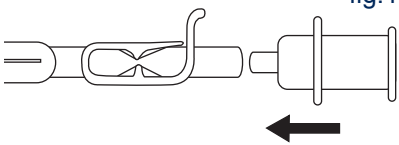
fig.16

Chapter 8 - Breath Bag Sample Collection Procedure

1. Remove the blue plastic plugs from each end of the breath bag.
2. Place two bag clamps over the inlet and outlet tubes of the breath bag. (fig. 17)
3. Insert a breath bag mouthpiece into the bag inlet tube of the breathbag. (fig. 18)
4. Ensure both bag clamps are disengaged/open, allowing air to pass through the bag.
5. Exhale gently through the bag at a steady rate.
6. Continue exhaling until you feel you have nearly emptied your lungs. This clears the dead air in the upper airspace of the lungs.
7. As soon as you feel your lungs are nearly empty, and end-tidal breath has almost been reached, engage/close the clamp at the outlet of the bag. (fig. 19)
8. Whilst still maintaining a steady flow, fill up the breathbag COMPLETELY with your end tidal breath, ensuring you do not inhale whilst doing this.
9. Engage the clamp at the inlet of the bag. (fig. 20)
10. Replace the blue plastic plugs in each end of the breath bag to ensure no breath is lost from the sample.
11. Hand over the bag to the consultant.

fig.17

fig.18



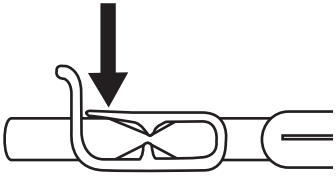


fig.19

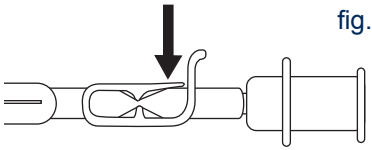


fig.20

Following these steps should ensure that a valid sample has been collected.

Chapter 9 - Maintenance

Calibrate in accordance with the procedure below

The mouthpiece cannot be cleaned or sterilized and should be disposed of appropriately after use.

Cleaning

Wipe the instrument surface with a product specifically developed for the purpose, such as Bedfont's Instrument Cleansing Wipes.

Servicing

It is recommended that the GastroCH$_4$ECK is serviced annually. Please contact your sales representative to arrange service. Servicing can be carried out by Bedfont Scientific Ltd or a suitable trained Level 2 Engineer.

If Methane Bench requires changing please contact Befont.

Calibration Procedure

Calibration of the GastroCH$_4$ECK should be carried out once a month during use and storage.

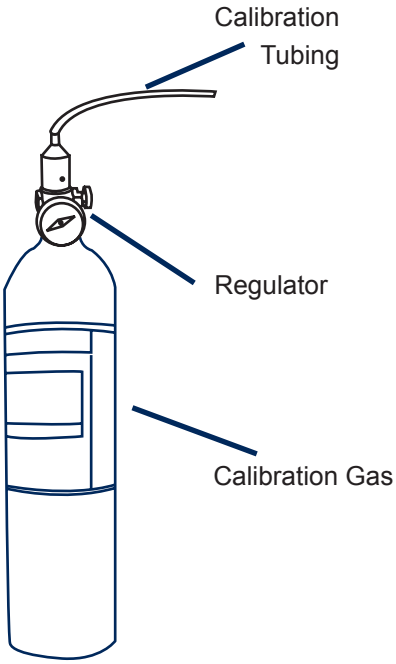
Methane (CH_4) and Hydrogen (H_2) Calibration

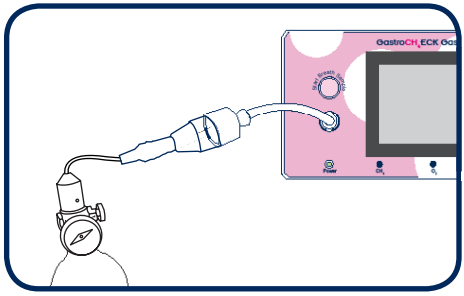
The certified combination gas canister supplied by Bedfont should be connected to the calibration line supplied and inserted into the sampling dock.

Press the "Breath Sample" Button the way you would initiate a real time breath test.

The monitor will initiate a Zeroing process. Wait until Breath hold is completed.

Open the regulator valve to start the flow of gas.





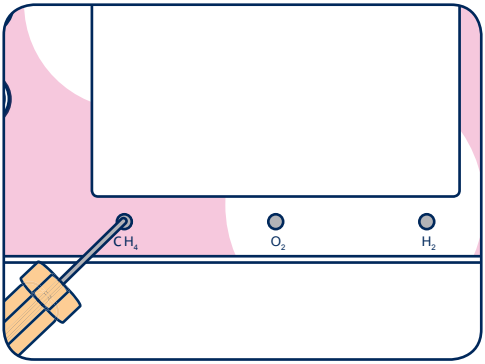
Allow approximately 45 seconds for the reading to stabilize.

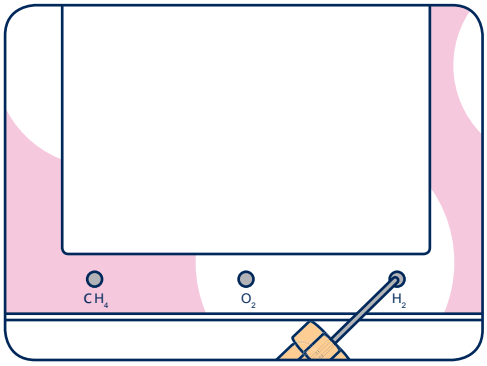
The displayed real time reading can then be adjusted to the value on the Cylinder by turning the “CH_4 span” potentiometer screw on the front of the monitor (See Instrument layout) using the calibration screwdriver supplied.

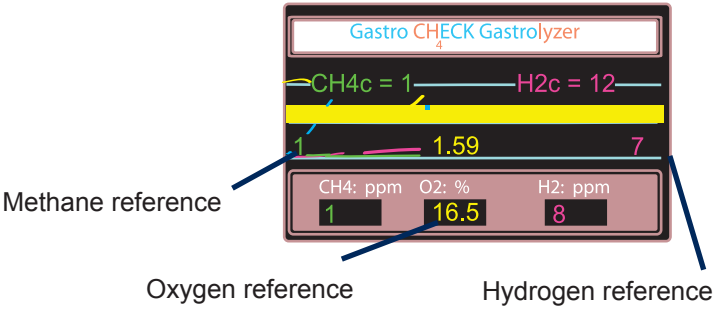
The displayed real time reading can then be adjusted to the value on the Cylinder by turning the “H_2 span” potentiometer screw on the front of the monitor (See Instrument layout) using the calibration screwdriver supplied.

Turn off the gas regulator and disconnect the tubing from the monitor.

Press the “Breath sample” Button to finish calibration.







Oxygen (O_2)

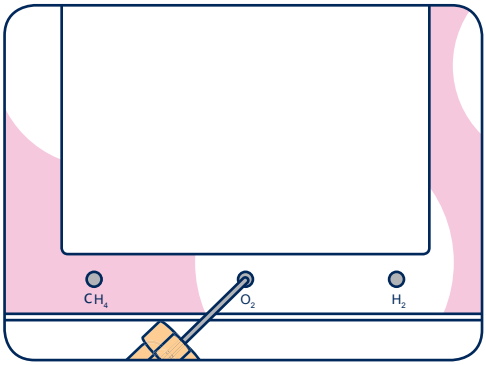
O_2 is calibrated using atmospheric air, therfore the calibration canister is not required.

Press the “Breath Sample” Button the way you would initiate a real time breath test.

Allow approximately 45 seconds for the reading to stabilize.

The displayed real time reading can then be adjusted to 20.9% by turning the “O_2 span” potentiometer screw on the front of the monitor (See Instrument layout) using the calibration screwdriver supplied.

Press the “Breath sample” Button to finish calibration.



Sensor Replacement

The hydrogen and oxygen sensors should be replaced every two years.

Chapter 10 - Returns Procedure

- If the equipment requires servicing or repair, please contact Bedfont's Customer Repairs department and visit www.bedfont.com/support before returning any goods. If the equipment was not purchased directly from Bedfont, please contact the local distributor.
- The Customer Repairs department will issue a Returns Number once the monitor serial number and a description of the fault are supplied.
- State the Returns Number when returning the monitor and ensure that full details, including telephone and fax numbers, are clearly provided along with a decontamination certificate.
- Bedfont advises using a courier service when returning monitors.
- It is advised that the instrument be returned in the original packaging supplied by Bedfont
- Confirmation will be issued when goods are received.
- An Engineer's Report and a quotation for the repair will be sent following investigation. This includes an Authorization Form.
- If the fault is covered by warranty, Bedfont will repair it and return it with an Engineer's Report, free of charge. If the monitor is found to simply require calibrating, a fee will be charged.
- If out of warranty, complete the Authorization Form included with the quotation to proceed with the repair or calibration. Ensure that an Official Purchase Order Number is included, and return the instrument to Bedfont. Contact the Customer Repairs department Specialist if you have any queries.
- If it is decided not to proceed with the repair, a handling fee will be charged. Ensure that the completed Authorization Form is returned to Bedfont with an Official Purchase Order Number.
- The equipment will be returned as soon as Bedfont has received all relevant paperwork. A carriage fee will be charged if the monitor is out of warranty.

Chapter 11 - Spares

GastroCH$_4$ECK Monitor	GASTROCHECK
Box of 100 GastroCH$_4$ECK Mouthpieces	GASTROCHECK-MP
Box of 250 GastroCH$_4$ECK Mouthpieces	GASTROCHECK-MP-XL
Box of 100 Mouthpieces and 100 450ml GastroCH$_4$ECK Breath Bags	GASTROCHECK-BAG
Box of 250 Mouthpieces and 250 450ml GastroCH$_4$ECK Breath Bags	GASTROCHECK-BAG-XL
Calibration Kit for GastroCH$_4$ECK Contains calibration canister, gas regulator and calibration tubing	CH4-H2-Calib-34
Calibration Gas Canister for GastroCH$_4$ECK	CH4-H2-CAN-34
Desiccant FIlter for GastroCH$_4$ECK	GASTROCHECK-DESS
Non-Alcoholic Monitor Sanitising Wipes	WIPES
USB Cable	USB-3F
Power Cable	BAT046
GastroCHART Software	BEDSOFT-GASTROCHECK
GastroCH$_4$ECK Manual	LAB389

Chapter 12 - Warranty

Bedfont Scientific Limited warrants the GastroCH$_4$ECK Gastrolyzer to be free of defects in materials and workmanship for a period of twenty four months from the date of shipment. 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, prepaid, to coVita.

Note: Sensors are guaranteed for a period of twelve months from the date of shipment from coVita.

These warranties are automatically invalidated if the products are repaired, altered, or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.

Do not dispose of any electronic equipment in domestic waste. At the end of the product's life, contact Bedfont or its distributor for disposal instructions.

The Oxygen and Hydrogen sensors are expected to last a duration of 2 years, it is advised that the sensors be replaced after the said period has elapsed.

The optical sensor will require annual servicing, please contact distributor to arrange for this activity.

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ISO 13485:2003
Cert No. MD 502905

CE 0086