Operating Manual

Issue 12 – 05/06

Please read this manual
Before using the GASTROCHECK

GASTROCHECK

Breath Hydrogen (H_2)
Monitor
Operating Manual

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Notes

Operating Manual Issue 11 - 03/04

Please read this manual
before using the Gastrolyzer 2

SCIENTIFICLTD

Warranty Introduction

EC60 Gastrolyzer 2

Hydrogen (H_2) is generated in the intestinal lumen by bacterial action on carbohydrates in the large or small intestine. This resultant H2 diffuses into the bloodstream and then to the alveoli, after which it can be detected in expiratory air. Levitt (1969)[1] demonstrated the correlation between intestinal lumen H_2 production and H excretion in expiratory air. Thus, accurate measurement of H_2 in parts per million (ppm) in expiratory air reveals abnormal breakdown and/or malabsorption of carbohydrates.

The Bedfont Gastrolyzer provides a simple, user-friendly sampling technique with specific H_2 detection, which is reliable, inexpensive, and rapid .[2]

Operation is straightforward. A T-piece sampling system enables end-expired breath to be sampled easily and hygienically, using one-time disposable cardboard tube mouthpieces. A modified low volume sampling technique enables children or people unable to give a sample to be monitored with a minimum of fuss, while neonates in incubators can be monitored simply by linking the Gastrolyzer to the expiratory limb of a ventilator. Alternatively, a face mask arrangement can be adopted.

The built-in 2-line LCD display shows the results within seconds, and stores the maximum value until 'switch off'. Thus technical analysis employing skilled personnel becomes redundant and, being fully portable with its own power source, the unit can be used in any location.

The Bedfont Gastrolyzer is supplied with full operating instructions, while maintenance amounts to no more than changing batteries when required, calibration at regular intervals and keeping clean by wiping down with a damp cloth.

The Gastrolyzer Portable Breath Hydrogen Monitor uses as its principle of detection a sealed electrochemical sensor which is specific to H_2. The sensor is of the micro fuel cell type, designed to be maintenance free and stable over long periods of time. Because of the unique diffusion barrier, the sensor is unaffected by normal temperatures and has a linear response to H_2 concentration independent of pressure.

The Gastrolyzer can be used for the analysis of Carbohydrate Breakdown Deficiency Detection, Carbohydrate Malabsorption Detection, Lactose Intolerance Diagnosis, Bacterial Overgrowth Diagnosis and Determination of Time Passage Through Gut.

[1] *Levitt, M.D. (1969): Production and excretion of Hydrogen gas in man. New Engl. J.Med. 281:122-127*

[2] *Fleming, S.C. (1990): Evaluation of hand-held Hydrogen monitor in the diagnosis of intestinal lactose deficiency. Ann.Clin.Biochem. 1990;499-500*

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Bedfont Scientific Ltd warrants portable instruments of its own manufacture (batteries, fuses, lamps, tubing, fittings and filters excepted) to be free of defects in materials and workmanship for a period of one year 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 item is returned intact, prepaid, to Bedfont Scientific Ltd or the local representative.
Note: sensors are guaranteed for a period of six months from the date of shipment from Bedfont.
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.

Troubleshooting Instrument Layout

The 2-line message display provides user messages, warnings and displays the patient's end-tidal breath H2 reading in ppm. In addition, the display shows a 15 second countdown during which the patient holds a lungful of breath before providing the end-tidal breath sample.
The Auto Zero enables the operator to zero the instrument before use, ensuring accurate readings every time.
1. 2-Line LCD message display
2. T-piece sampling system
3. Disposable cardboard mouthpiece
4. ON/OFF Switch
5. ZERO button
6. GO button
7. Battery Compartment
8. Span adjustment
9. Calibration adaptor
10. Face mask sampling system

Key

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What to do IF....

There is no LCD or panel response under gas when sampling with new batteries?
LCD readings are erratic and unsteady?
The Gastrolyzer returns consistently low readings or none at all?
The LOW BATTERY warning message appears on the display?
Your Gastrolyzer is dropped or immersed in liquid?

Note

Return the equipment immediately to Bedfont Scientific Ltd or the local representative. Under no circumstances attempt to locate and correct the fault yourself.
Check battery strength by switching the unit off and then back on again. If the LOW BATTERY warning message appears, switch unit off and replace battery.
Check the condition of the sampling system. Under frequent use, saliva deposits can cause valves to stick. DO NOT attempt to clean them but replace the complete sampling system immediately.
If, after replacement, there is no improvement in performance, return the Gastrolyzer to Bedfont Scientific Ltd or the local representative.
Switch unit off and change battery immediately. Replacement battery must an alkaline PP3 9V battery or equivalent.
Return the instrument to Bedfont Scientific Ltd or the local representative for checking.
: the instrument can be wiped with a damp cloth using a mild detergent.

Never, under any circumstances, attempt to immerse the sensor in any fluid or apply neat alcohol. The sensor is a sealed unit, which does not need sterilising. Do not attempt to replace or modify the sensor yourself.
All accessories supplied are disposable. Replacement parts can be purchased from Bedfont Scientific Ltd or the local representative.

Operation Contd. Cleaning & Sterilisation

Manual Zeroing
Taking a Test Reading

The instrument can be manually zeroed at any time. Ensure that no gas is connected and the T-piece is removed before continuing. To perform a manual zero press the red Zero button. The top line of the display shows:

PLEASE WAIT

The bottom line shows:

RemoveT-Piece

Followed by:

Ensure No Gas

Followed by:

* ZEROING *

When complete the instrument produces a short beep and displays:

Ready
Gastrolyzer 2

Connect the T-Piece sampling system with cardboard disposable mouthpiece attached. Ensure all connections and sampling system are pushed firmly in place to prevent leakage of sample.
Press the blue GO button at the same time asking the patient to hold their breath during the 15 second countdown. The display shows:

Breath Hold
XX secs

Where XX counts down from 15 to 0 in 1-second intervals. The last 3 secs are accompanied by short bleeps and a final long beep. The top line of the display then shows:

!! Exhale !!

The patient should then exhale slowly and gently into the mouthpiece, emptying the lungs as far as possible.
The case of the instrument may be cleaned by wiping with a cloth moistened with water.
Under no circumstances should the instrument be immersed in liquid.
The T-Piece can be cleaned using a soap and water solution; to clean under the valve seats lift the white valve flaps using a cotton bud. Care must be taken not to crease or damage the white flap valve as this may prevent correct operation.
Once the T-piece has been cleaned it can be sterilised a maximum of 10 times by autoclaving at 121 °C for 10 minutes. Ensure that the white flap valves are in place and free from distortion after the procedure.
Ensure the T-Piece is completely dry before refitting to the instrument.
Alternatively the T-Piece can be cost effectively replaced. We strongly recommend single use of the T-Piece when there is particular concern about possible cross contamination.
Replacement T-Pieces are readily available from Bedfont Scientific Limited or our approved agents.

Syringe Calibration Operation Contd.

When starting a new reading, if the instrument detects the presence of gas in the sampling system the test will NOT be allowed to start, the instrument emits a low beep and the display will show:

!! Not Zero !!
Ensure No Gas
If this occurs remove the T-piece and ensure the sensor is clear of gas before attempting another reading.
Before proceeding with this test method the instrument must be calibrated using a syringe see Syringe Calibration section
It is also possible to supply a sample using a syringe kit instead of directly from exhaled breath. Under this situation connect the sampling plug into the sensor housing of the instrument. Ensure it is firmly pushed in place to prevent leakage of the gas.
Connect the syringe to the sampling plug using the plastic tubing (see photograph opposite). Start the test in the normal way and when the display shows:
!! Exhale !!
Depress the syringe (note: you will feel a high back pressure, which is to protect the sensor) and maintain steady pressure. The instrument will then display the reading in the normal manner.

Taking a Reading with a Syringe (Low Volume Sampling Kit)

If the normal method of taking readings is to use a syringe then it is recommended to calibrate the instrument using a syringe to ensure maximum accuracy.
The syringe calibration method is similar to the normal calibration method except that a syringe kit is required in addition to the normal calibration kit.
The syringe kit consists of a syringe, 2 pieces of tubing, a tubing T-piece and a sampling plug.
Connect the syringe to the calibration gas cylinder as indicated in the photograph opposite.
Connect the sampling plug into the sensor housing of the instrument. Ensure it is firmly pushed in place to prevent leakage of the gas.
Open the fine control valve and allow the gas to flow at 1.0 litres/minute. To maintain this, adjust the flow so the ball in the flow indicator remains at the centre line (see diagram below).
1.5 l/m
1.0 l/m
0.5 l/m

Notes Contents

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Pack Contents List Specification

Gas Detected: Hydrogen (H_2)
Concentration Range: 0-250 ppm
Calibration Flowrate: 0.5 litres/minute (1.0 litres/minute with syringe)
Detection Principle: Electrochemical sensor

Accuracy: +/-2% of reading
Carbon Monoxide
Cross Interference: <15%
Alcohol Cross Interference: Negligible
Display: Liquid Crystal Display
Power Input: PP3 alkaline battery (9v, 6LF22/Equiv)
: to avoid long start up times, ensure Gastrolyzer is switched OFF if battery is removed.
Warm up Time: Typically less than 120 seconds
Response Time: Under 30 seconds to 90% FSD
Drift: Typically less than 2% signal loss/month
o Operating Temperature Range: 0-40 C
Operating Humidity Range: 0-100%
Sensor Operating Life: 2-3 years. 6 months warranty
Sensor Sensitivity: 1ppm
Dimensions: 63 (D) x 85 (W) x 144 (H)mm
Weight Including Battery: Approx. 225 g
Construction: Plastic
o Recommended Storage Temp: 0-30 C
Meets the essential requirements of the Medical Device Directive 93/42/EEC Annex V. Certificate No. CE:01469.

Note

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1. Gastrolyzer instrument
2. T-piece sampling system
3. Cardboard disposable mouthpieces (x3)
4. Calibration adaptor
5. Adult face mask
6. Child face mask
7. Infant face mask
8. Face mask sampling system
9. Calibration screwdriver
10. Battery
11. Operating manual
12. Carrying case

Operation Spares

Power On

NOTE

Ensure battery is located in battery compartment. Switch ON/OFF switch to ON position. If low battery warning message is displayed, turn the unit off and replace the 9-volt alkaline battery, which is located in the battery compartment.
: The batteries should be removed if the

instrument is not used for periods greater than one month.
After power up the display will show:
Bedfont
Gastrolyzer 2
The top line then displays:
* ZEROING *
If appropriate the display may show:
SENSOR HIGH or SENSOR LOW
When Zeroing is complete the display will show:
SENSOR O.K.
This is followed by 2 short beeps and a long beep and the following display:
Ready
Gastrolyzer 2
The power on zeroing process can take up to 2 minutes.

Part Number Description

EC60-T/P-V Pack of 10 disposable T-pieces
EC60-MP-200 Box of 200 disposable mouthpieces
EC60-Adapt-V Adaptor to allow new T-piece to be used with Gastrolyzer 1
EC60SSS Syringe sampling system for low volume testing.
Includes low volume plug, syringe and connectors.
EC60-ISS Infant/child sampling system
EC60-IM Infant face mask
EC60-MM Medium sized face mask
EC60-AM Adult face mask
EC60-CA Calibration adaptor
EC60-COS Replacement sensor
PP3-Batts Replacement PP3 9v battery
EC60-Man Replacement manual
EC-60-CC5 Carry case to house instrument and accessories

Operation Contd. Syringe Calibration Contd.

Draw a sample slowly into the syringe. Disconnect syringe from the T-piece sampling system and connect to sampling plug (see photograph below).
Turn off the gas flow, remove T-piece sampling system and disconnect the calibration adaptor. Unscrew the fine control valve and flow indicator from the gas can and store safely. If valve is left in the can, the gas could escape.
To start the calibration process press the blue GO button followed by the red Zero button within 3 seconds. The display shows:
Calibrate
XXppm H_2
Where XX is the real-time ppm reading of the applied calibration gas, not the peak held value as with a normal reading.
Depress the syringe (note: you will feel a high back pressure, which is to protect the sensor) and maintain steady pressure. If after the syringe has been emptied the ppm reading does not show between 195 and 205ppm, using the screwdriver, adjust the SPAN control on the underside of the instrument, until a reading of between 195 and 205ppm is displayed. Turning clockwise will increase the reading and turning anti-clockwise will decrease it.
When complete press the GO button to exit the Calibration mode.

A powerful exhalation may dislodge the valve and will not necessarily provide the desired end-tidal air sample. Alternatively if children or infants are to be monitored, a modified sampling technique can be used. This consists of a specially constructed breathing system, which allows exhaled breath to be directed to the instrument's sensor for analysis. The appropriate size face mask should be placed over the nose and mouth of the patient, care being taken to avoid leaks around the mask cushion. The patient can then

breathe normally, whilst being encouraged to exhale as much as possible.
To use the face mask select the appropriate mask and attach to the face mask sampling system. This is then connected to the T-piece in place of the mouthpiece. See photograph opposite.
This procedure can start either after the 15-second countdown or during it. The display can then be observed to ensure the maximum reading is obtained.
: People with lung diseases or chest ailments may not be able to achieve the 15-second breath-hold. In such cases, initiate the 15-second countdown, wait for 0ppm to show on the LCD, and then instruct the patient to inhale. Hold breath as long as possible, and exhale through the Sampling System mouthpiece. Alternatively, if people with contagious diseases are being analysed, Bedfont recommend the Sampling System be replaced after use.
The top line of the display will show a bar graph of the real time reading and the lower line shows:

XXppm H_2

Where XX is the peak held reading in ppm. This reading will be held until the instrument is switched off or another test is started.
When the test is completed the top display shows:

Ready

XXppm H_2

Where XX is the peak held reading in ppm from the latest test. The instrument is now ready to take another test reading.
: Always ensure the T-piece is removed between readings.

NOTE

IMPORTANT

Calibration Calibration Contd.

For continued accurate use, calibration on a monthly basis is recommended. To calibrate the instrument a Bedfont calibration kit is required consisting of a gas can, fine control valve and flow indicator and plastic tubing.
Ensuring that the valve is in the OFF position (turn the valve knob clockwise), screw the fine control valve and flow indicator assembly to the gas can. This is best done by screwing the gas can into the valve.
With the tubing, connect the calibration adaptor and the flow indicator. Warming the end of the tubing using a hair dryer or lighter will assist connection. Insert the calibration adaptor into the T-piece sampling system in place of the mouthpiece. Insert the T-piece sampling system into the Gastrolyzer sensor housing, ensuring that all connections and sampling system are firmly pushed in place to prevent leakage of the calibration gas (see photograph opposite).
Open the fine control valve and allow the gas to flow at 0.5 litres/minute. To maintain this, adjust the flow so the ball in the Flow Indicator remains at the lower line (see diagram opposite).
To start the calibration process press the blue GO button followed by the red Zero button within 3 seconds. The display shows:

Calibrate

XXppm H_2

Where XX is the real-time ppm reading of the applied calibration gas, not the peak held value as with a normal reading.

1.5 l/m

1.0 l/m

0.5 l/m

Allow gas to flow through the instrument for 1½ minutes to ensure accurate calibration, again monitoring the rate of flow.

If after 1½ minutes, the ppm reading does not show between 195 and 205ppm, using the screwdriver, adjust the SPAN control on the underside of the instrument, until a reading of between 195 and 205ppm is displayed. Turning clockwise will increase the reading and turning anti-clockwise will decrease it.

When complete press the GO button to exit the Calibration mode.

Turn off the gas flow, remove T-piece sampling system and disconnect the calibration adaptor. Unscrew the fine control valve and flow indicator from the gas can and store safely. If valve is left in the can, the gas could escape.