

Gastro+ Gastrolyzer®



Operating Manual



CE
0086

breath analysis is the new blood test

www.bedfont.com

the 1990s, the number of people in the UK who are employed in the public sector has increased from 10.5 million to 12.5 million, and the number of people in the public sector who are employed in health care has increased from 1.5 million to 2.5 million (Department of Health 2000).

There are a number of reasons for this increase. One of the main reasons is the increasing demand for health care services. The population of the UK is ageing, and there is a growing number of people with chronic conditions such as heart disease, diabetes, and asthma. This has led to an increase in the number of people who are hospitalised and the length of their stays. In addition, there has been a growing emphasis on preventive care, which has led to an increase in the number of people who are screened for cancer and other diseases.

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Intended Use

The Gastro⁺ Gastrolyzer[®] is a breath hydrogen monitor used to measure hydrogen levels in expired breath. It is intended for multi-patient use by healthcare professionals in a clinical environment.

Introduction

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

Operation of the monitor is straightforward. A D-piece sampling system enables end-expired breath to be sampled easily and hygienically, using single-use disposable cardboard Steribreath™ mouthpieces and disposable face masks. A colour touch screen ensures ease of operation and users can view results in a tabular or graphical format.

The Gastro⁺ can be used to indicate the following disorders:

- Carbohydrate breakdown deficiency
- Carbohydrate malabsorption
- Lactose intolerance²
- Bacterial overgrowth
- Determination of time passage through the 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




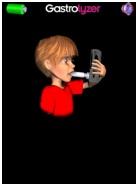
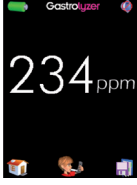


Warnings

- When cleaning the monitor, never use alcohol, cleaning agents containing alcohol, or other organic solvents, as these vapours will damage the H₂ sensor inside.
- Under no circumstances should the instrument be immersed in or splashed with liquid.
- The device cannot diagnose a specific condition; only indicate a possible range of conditions.
- People with lung disease or chest ailments may not be able to achieve the full breath-hold. In such cases, the user should inhale and hold their breath for as long as possible when the breath test is started, and exhale, if necessary, before the countdown has completed. Alternatively, the user can use the face mask sampling mode.
- If the  icon is displayed during start-up, calibration is due. Please refer to page 13 for instructions. The unit may give false readings if not calibrated.
- If the  icon is displayed during start-up, the D-piece requires changing. It is recommended that the D-piece is changed every month, or more frequently if it is visibly soiled.
- The battery life is indicated by the  icon. When the  icon is displayed, the batteries should be changed.
- The disposable Steribreath™ mouthpieces are for single use only. Reuse can increase the risk of cross-infection.
- See Bedfont's Infection Control and Maintenance Guidelines for further information on infection control.
- Please do not attempt to modify the equipment in any way or use accessories not specified by the manufacturer. Any attempt to do so will invalidate the warranty and may compromise the safety of the device.
- Bedfont will make available on request service training to appropriately qualified personnel.
- Measurements from the face mask sampling method may be lower than when using the mouthpiece. This should be considered when interpreting the results.
- Do not cover the exhaust port as this may affect the accuracy of the test.
- Remove the D-piece between uses to allow fresh air to circulate around the sensor.
- The Gastro⁺ must be switched on in fresh air to ensure an accurate zero.
- The USB port should be used to connect to a PC, to run the GastroCHART PC software. Please ensure the monitor is only connected to a computer manufactured law EN60950.
- The operator must not touch the battery terminals and the patient simultaneously.

Contraindications

- Temperature may affect the accuracy of the Gastro⁺. The instrument should be calibrated at 21°C (±4°C). If the Gastro⁺ is used at a lower temperature than when it was calibrated, readings may be lower. When used at a higher temperature than calibrated, readings may be higher.

Quick Start Guide

- 1 Press and hold the on/off button until the display becomes active, then release the button.
- 2 Allow the unit to display the home screen, then insert the D-piece into the instrument and fit a new Steribreath™ mouthpiece or a face mask.
- 3 Touch the  icon to start a breath test. Alternatively, if a face mask is being used, press the  .
- 4 If  has been touched, the breath-hold countdown will begin. The patient should inhale deeply and hold their breath while the display counts down to zero. If the patient is unable to hold their breath for the full countdown, see Warnings on page 4 or Settings on page 12. Please see step 6 if the face mask is being used.
 
- 5 An audio bleep will sound during the last three seconds of the countdown.
- 6 At the end of the countdown, the patient should blow slowly into the mouthpiece, aiming to empty their lungs completely. If the face mask is being used, the patient should breathe normally but be encouraged to exhale as much as possible.
 
- 7 The ppm value will rise, and the highest level will remain on the screen.
 
- 8 Remove and dispose of the Steribreath™ mouthpiece or face mask safely.
- 9 Remove the D-piece between tests to allow fresh air to circulate around the sensor.
- 10 Touch the  or  icon at bottom of the screen to perform another breath test. If using a mouthpiece, a new one should be fitted. If using the facemask, this can continue to be used.
- 11 To switch off, press and hold the on/off button for three seconds. The unit will auto power-off after 45 minutes of inactivity.



Specification

| | |
|--------------------------------------|---|
| Concentration range: | 0-500ppm hydrogen (H ₂) |
| Display: | Colour LCD with 1ppm increments |
| Detection principle: | Electrochemical sensor |
| Accuracy (repeatability of reading): | ±10% |
| Carbon monoxide cross-sensitivity: | ±<0% |
| Batteries: | 3 x AA (LR6 or equivalent) alkaline batteries 1 x CR2032 Lithium coin cell (3v) |
| Response time: | Typically <45 seconds |
| Operating temperature range: | 15-35°C (storage 0-50°C) |
| Operating humidity: | 10-90% (storage 0-95%) non-condensing |
| Sensor operating life: | 2-3 years, 12 month warranty |
| Sensor sensitivity: | 1ppm |
| Transport/Storage Humidity: | 15%-90% rh non condensing |
| Dimensions: | Approx. 44 x 77 x 138 mm |
| Weight: | Approx. 250g including batteries |
| Construction: | Case: Polycarbonate/ABS blend with elastomeric overmould. D-piece: Polypropylene |

Symbols

 Direct Current

Degree of protection against electric shock:  Type BF applied part

Type of protection against electric shock: Internally Powered Equipment



Please refer to the warnings and safety notes in the manual



Consult instructions for use

Degree of protection against ingress of liquid: IPX0 - not protected against water ingress

Degree of safety 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.

Environment

The Gastro+ 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. This equipment should be moved if necessary to avoid interference.

Pack Contents List

- 1 Monitor
- 2 Operation Instructions
- 3 Box of 12 D-pieces
- 4 Steribreath™ mouthpieces
- 5 3 x AA batteries

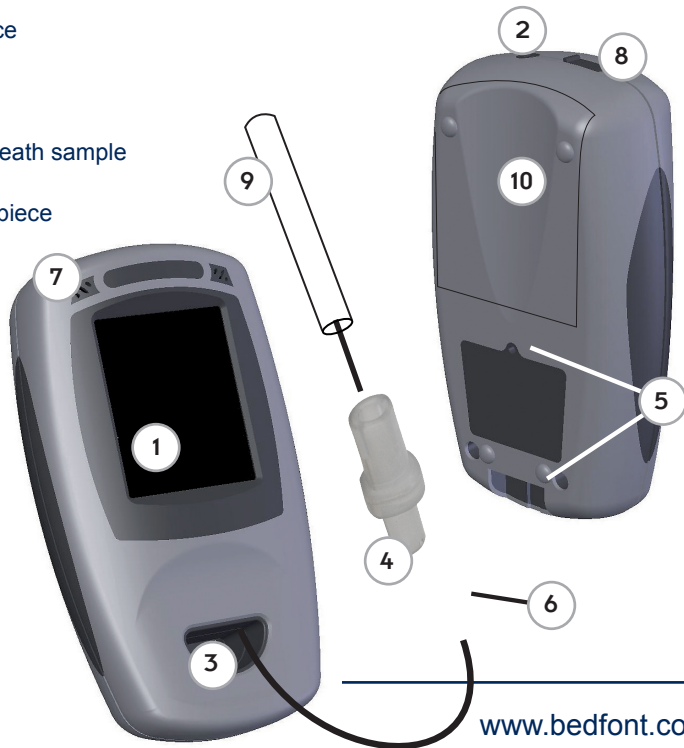
Plus:

- Infection Control and Maintenance Guidelines
- Warranty Registration Card
- USB cable
- GastroCHART software CD



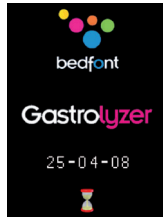
Instrument Layout

- 1 Display
- 2 On/off button
- 3 Aperture for D-piece
- 4 D-piece
- 5 Exhaust port for breath sample
- 6 Locating lug on D-piece
- 7 Sounder
- 8 USB connector
- 9 Steribreath™ mouthpiece
- 10 Battery compartment



Display Symbols

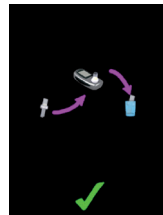
1. Start-up screen:



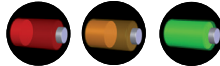
2. Calibration prompt start-up screen:



3. D-piece renewal prompt start-up screen:



4. Battery condition:



5. Sounder:



6. Return to main menu:



7. Return to previous menu:



8. Start breath test:



9. Settings:



10. Patient data:



11. Patient data in table format:



12. Patient data in chart format:



13. Inhale:



14. Breath-hold and countdown:



15. Exhale for breath test:



16. Peak H₂ reading (ppm):



17. New breath test:



18. Face mask option:



19. Save breath test:



20. Set instrument zero in fresh air:



21. Apply calibration gas at 100ppm:



22. Calibration/zero: Pass



Fail



23. Retry calibration/zero:



24. Zeroing required before calibration:



25. Breath-hold timer setting:



26. Set date/time:



27. System information screen:



28. Contact Bedford or distributor for help:



Maintenance

Calibrate in accordance with the procedure on page 13.

Replace batteries when indicated by .

Replace the D-piece every month, or more frequently if visibly soiled or contaminated. The D-piece cannot be cleaned or sterilised. The Gastro+ will give a reminder during the start-up when the D-piece should be replaced – see Operation, page 10.

Remove the D-piece by gently pulling it out of the front of the instrument.

Batteries should be removed if the instrument is not likely to be used for some time.


Bedfont recommend an annual service in order to check sensor and component parts performance.



The sensor should be replaced every two years.


Cleaning





Wipe the instrument and external D-piece surfaces with a product specifically developed for the purpose, such as Bedfont's Instrument Cleansing Wipes – see Warnings, page 4.

Operation

- Ensure that 3 × AA alkaline batteries are correctly inserted.
- The touch screen controls all functions once the instrument is switched on.
- Press and hold the on/off button for three seconds until the display becomes active, then release the button. The start-up screen will be displayed for a one-minute warm-up period before the main menu appears.
- If a  and a ppm value are shown rather than the main menu, the instrument has failed to zero during start-up. Ensure that the instrument is in fresh air, then touch the screen to repeat the start-up test. If it fails again, please see Troubleshooting, page 15.



Note: When the Gastro+ requires calibration (every month), the calibration prompt screen will appear. Touch  to accept, or  to calibrate later.



When the D-piece requires changing (recommended monthly), the D-piece renewal prompt screen will appear. Touch  to accept. The reminder will be reset and will prompt again in 28 days.

- The main menu displays four symbols:
 - 1 Breath test 
 - 2 Face mask test 
 - 3 Settings 
 - 4 Patient select 

Note: The patient select icon will not be accessible until patient data has been downloaded from GastroCHART.





Breath Test

- Attach a D-piece and a new Steribreath™ mouthpiece, or a face mask, to the Gastro⁺. Check that all connections are pushed firmly together.
- To start a breath test, touch the  or  icon.









Note: If the display shows  it means that the sensor has not settled to zero before the test. The display will show a  once the sensor has settled and the unit is ready for use. Removing the D-piece will accelerate the zero process.

- The patient should inhale as deeply as possible and hold their breath throughout the on-screen countdown. An audio beep will sound during the last three seconds of the countdown.
- Exhale slowly but gently into the mouthpiece, aiming to empty the lungs as far as possible. If the face mask is being used, the patient should breathe normally but be encouraged to exhale as much as possible.

Note: If the patient cannot hold their breath for the full countdown, they should commence exhalation at a comfortable point, but ensure that they exhale completely – see Timer settings, page 12, and Warnings, page 4. Alternatively, they can use the face mask option.

- The display will show a rising ppm value.
- The peak reading will be shown on the display. The test is complete when the     icons are displayed.
- Remove and dispose of the Steribreath™

mouthpiece or face mask safely.

- Remove the D-piece between tests to allow fresh air to circulate around the unit. It is advisable to wash your hands after removing the D-piece.
- To start another breath test, fit a new Steribreath™ mouthpiece or face mask and touch the  or  icon accordingly.
- Touch  to return to the main menu.
- Touch  to save the result to the patient database. Select the patient using the  and  arrows and touch  to save or  to cancel. Selecting either option will take you back to the main menu.

Note: This is only possible if patient data has been downloaded to the Gastro⁺ via GastroCHART.

- If no further tests are required, press and hold the on/off button for three seconds until the Gastro⁺ turns off. The Gastro⁺ will automatically turn off after 45 minutes of inactivity.

Face Masks

If children or infants are to be monitored, a face mask sampling technique can be used. An appropriately-sized face mask should be placed over the nose and mouth of the patient, taking care to avoid leaks around the mask cushion. The patient can then breathe normally, but should be encouraged to exhale as much as possible.


Settings

The settings menu allows access to the following functions:

- Sounder
- Breath-hold countdown timer
- Set date/time
- System information
- Zero/calibration

Sounder




The operation of the sounder is indicated by the small symbol on the top line of the display.

To switch the sounder on or off, touch the large  icon on the Settings menu. The large sounder symbol and the smaller symbol on the top line of the display will indicate whether the sounder is on or off.

If the sounder has been turned off, it will still operate during the last three seconds of the breath-hold countdown.

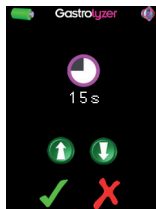
Breath-hold Countdown Timer

It is possible to change the length of time that the patient should try to hold their breath – see Warnings, page 4.


Touch  in the Settings menu and use  or  to change the timer setting.


Press  to save or  to cancel.



Return to main menu.





Date and Time

The date and time is used when saving patient data to accurately record when tests were carried out. To change the date and time, touch  in the Settings menu.







Touch the required field and use  and  to change.





Press  to save or  to cancel. Return to main menu.

System Information

Touch  to access system information such as the software version. Touch  to return to the previous menu.


Zero/Calibration

- The instrument should be calibrated at 21°C (±4°C) the temperature at which it is expected to be used – see Warnings, page 4.
 - The Gastro⁺ is calibrated at 21°C (±4°C) before leaving Bedfont.
 - The Gastro⁺ should be calibrated at least every month. The Gastro⁺ will give a reminder during start-up when calibration is due.
 - The calibration gas required is 100ppm hydrogen in air.
 - Turn the instrument on in the normal way. Select  from the Settings menu.
 - The  is displayed when the monitor has not been zeroed prior to calibration.
 - Ensure that the instrument is surrounded by fresh air. Touch  to begin the zeroing. If the zeroing has been successful, a  will be displayed. If the zeroing fails, an  will be displayed – see Troubleshooting, page 15, if this happens.
 - Touch  to accept the zero and return to the calibration/zero menu.
 - Ensure the calibration gas valve is in the off position.
 - 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.
 - Open the fine control valve by turning the control knob anticlockwise and



1. Fine control valve
2. Flow indicator
- allow the gas to flow at 0.5 litres per minute.
- Touch  to begin calibration.
 - On the third beep connect calibration apparatus as illustrated.
 - To achieve this, adjust the flow so that the ball in the flow indicator remains on the lower line.
 - As the 100ppm H₂ calibration gas is applied, the displayed ppm reading will rise.
 - Monitor the rate of flow and continue to apply the gas.
 - If the final displayed reading is between 84 and 116ppm, the calibration value will be automatically set in the instrument as 100ppm and a  will be displayed to show a successful calibration. If the displayed reading is outside these limits, the calibration fails, and a  will be displayed - see Troubleshooting page 15 if this happens.
 - Touch  to accept the calibration and return to the calibration/zero menu.
 - Turn off the gas flow, remove the D-piece and disconnect the calibration adapter.
 - Unscrew the fine control valve and flow indicator from the gas can and store safely. If the valve is left attached to the can, the gas could escape.
 - The Gastro⁺ is now calibrated and ready for use.



Patient Information

Touch  on the main menu to access patient information. This icon will remain inactive until patient data has been downloaded via GastroCHART.








Touch  and  to highlight the required patient.

Touch  to view data in table format or  to view in graphical format.

Touch  to return to the previous menu.

Note: The Gastro+ should not be used in live test mode via the PC software. It should only be connected to the PC for data upload.

Troubleshooting

- If the unit fails to turn on properly, or if the low battery symbol is showing, replace the 3 × AA alkaline batteries. Ensure that the batteries are inserted correctly, matching the symbols moulded into the plastic.
- If the display shows  after zeroing, a second attempt can be made to zero the unit in fresh air. Check that the unit is in fresh air and the exhaust is not covered then touch  to restart the zeroing process. If, after a third zeroing attempt, the display shows  again, the unit needs to be reset using the Calibration Unlock Tool, which is available as a download from the Support Site at www.bedfont.com/support. The monitor will need to be connected to a PC using the USB cable provided. Once the download has been run, the monitor can be unlocked. It is then possible to restart the unit and attempt the zeroing process again. If you are still experiencing problems, please contact Bedfont's Customer Service Specialist.
- If the display shows  after an attempted calibration with 100ppm H₂ gas, it means that the gas value was not within the permitted limits. The reading is displayed below the . If the value is much lower than 100ppm, there may have been a problem with the supply of gas from the cylinder. If the value is much higher than 100ppm, the wrong concentration of calibration gas may have been used or the exhaust has been covered. In either case, check the cylinder, connections and flow rate before touching  to repeat the calibration process. If a  still appears after a third attempt to calibrate the instrument, please download the Calibration Unlock Tool, as described. If you are still experiencing problems, please contact Bedfont's Customer Service Specialist. The unit can be restarted with the previous calibration settings, or the calibration process can be begun again.

Returns Procedure

Should equipment require servicing, please contact Bedfont's Customer Service Specialist before returning any goods. If equipment was not purchased directly from Bedfont, please contact the local distributor.

- When the monitor serial number and description of the fault have been supplied, the Customer Service Specialist will issue a Returns Number.
- State the Returns Number when returning the monitor, ensuring that full contact details, including telephone and fax numbers, are clearly provided.
- Bedfont advise that you use a courier service when returning monitors.
- Confirmation will be sent when goods are received.
- An Engineer's Report and a quotation for the repair, including an Authorisation Form, will be sent following investigation.
- If the monitor is still in 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 the monitor is out of warranty, complete the Authorisation Form with the quotation to proceed with the repair or calibration. Ensure that an Official Purchase Order Number is included, and return the form to Bedfont. Contact the Customer Service Specialist if you have any queries.
- A handling fee will be charged if it is decided not to proceed with the repair. Ensure that the completed Authorisation Form is returned with an Official Purchase Order Number.
- The equipment will be returned as soon as Bedfont have received all the relevant paperwork. A carriage fee will be charged if the monitor is no longer in warranty.

Spares

| Spares: | Part Codes: |
|--|-------------------------------------|
| D-pieces | D-PIECE |
| 250 Steribreath mouthpieces | STERIBREATH- MP |
| Calibration gas and kits: 100ppm H ₂ in air calibration gas 100ppm H ₂ in air calibration kit | 020-14-12010-V 020-14-12010K-V |
| Face masks Adult face mask Child face mask Infant face mask | EC80-IM-V EC60-MM-V EC60-AM-V |
| Instrument cleansing wipes | WIPE-BB |
| AA alkaline batteries | PI-BATTS-V |
| Stylus | FXS399 |
| Cleaning Cloth | FXS400 |

The above spares are available from Bedfont Scientific Ltd, UK. For spares availability in all other countries, contact your local distributor. It is recommended that only Bedfont spares are used.

Warranty

Bedfont Scientific Ltd warrants the Gastro+ (batteries excepted) to be free of defect 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 Bedfont Scientific Ltd or the local representative.

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

Bedfont recommend an annual service of the Gastro+ and a sensor replacement every 2 years.

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.

Single use consumables and accessories should be disposed of inline with clinical waste guidelines.



At the end of the product's life, do not dispose of any electronic instrument or batteries in the domestic waste. Contact Bedfont or your local distributor for disposal instructions.



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ISO 9001:2008

Cert No. FM 31664

ISO 13485:2003

Cert No. MD 502905

Issue 13- January 2014, Part No: LAB283

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