Gastro+™ Gastrolyzer®

User manual

CE 0086

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Contents

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Gastro⁺™ Gastrolyzer®

Intended use

The Gastro⁺™ Gastrolyzer® is a breath hydrogen (H_2) monitor used to measure hydrogen levels in expired breath. It is intended for multi-patient use by healthcare professionals in a clinical environment.

Introduction

H_2 is generated in the intestinal lumen by bacterial action on carbohydrates in the small or large intestine. Once the resultant H_2 is diffused into the bloodstream it is transported to the alveoli and then can be detected in expiratory air. Levitt[1] demonstrated the correlation between intestinal lumen H_2 production and H_2 excretion in expiratory air. Accurate measurement of H_2 in parts per million (ppm) in expiratory air reveals intolerance and/or malabsorption of carbohydrates; or bacterial overgrowth.

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 SteriBreath™ mouthpieces and disposable face masks.

The Gastro⁺™ can be used to aid in the diagnosis of the following disorders:

- Carbohydrate intolerance
- Carbohydrate malabsorption
- Intestinal bacterial overgrowth
- Investigation of intestinal transit time

Taking a breath test

1. Attach a breath sampling D-piece™ and a new SteriBreath™ mouthpiece.
2. Turn on the monitor by pressing the power button once.
3. Press .
4. If is shown, the sensor is still stabilising.
5. Inhale and hold breath for the pre-set 15 second countdown, as shown on screen. If unable to hold breath for full 15 seconds, the timer can be adjusted in the settings.
6. A beep will sound during the last three seconds of the countdown.
7. Blow slowly into mouthpiece, aiming to empty lungs completely.
8. The ppm levels will rise and hold on-screen.
9. When the test is finished will appear at the bottom of the screen.
10. To repeat breath test, press and repeat steps 5-8.
11. To return to the home screen, press .
12. To save the reading, press and select the relevant patient profile.
13. Remove the D-piece™ between tests to purge sensor with fresh air.

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14. To switch off, press and hold the power button for 3 seconds, unit will also power off after 45 minutes of inactivity to save power.

Taking a face mask test

1. Attach a new face mask sampling system.
2. Turn on the monitor by pressing the power button once.
3. Press [icon].
4. If [icon] is shown, the sensor is still stabilising.
5. Inhale and exhale into the face mask, the device will take the reading in real-time.
6. The ppm levels will rise and hold at the peak level, when this has stopped rising for a period of 5 consecutive seconds the test result can be recorded and the test stopped.
7. When the test is finished [icons] will appear at the bottom of the screen.
8. To repeat breath test, press [icon] and repeat steps 3-8.
9. Remove the face mask sampling system between tests to purge sensor with fresh air.
10. To switch off, press and hold the power button for 3 seconds, unit will also power off after 45 minutes of inactivity to save power.

Adding a patient profile

The Gastro⁺™ Gastrolyzer® allows up to 10 patient profiles to be set-up on the device in order to record readings to a specific patient profile and then downloaded later using GastroCHART™. This can be done by following the steps below:

1. Press [icon] on the main screen.
2. Press a patient profile slot [1] to go to the edit screen.
3. Press the patient profile slot again [1] to enter the name for the patient using the keyboard provided.
4. Once you are happy with the name or ID, press [icon].
5. You have now successfully set-up a patient profile; more can be set-up by pressing [icon] to return to the patient profiles screen and repeating steps 2-4.
6. Alternatively you can return to the home screen by pressing [icon].

Conducting automatic patient breath tests

Warning: Ensure batteries are full or device is connected to computer USB port (it will be powered by the USB). If the device loses power during the automatic testing mode only saved results will remain on the device and the protocol timings will be lost.

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The Gastro⁺™ Gastrolyzer® allows you to set up automatic testing for up to 10 patients in one session, which can be very time-saving in a busy clinic. This can be done by following these steps:

1. Press on the main screen; this will take you to the patient database screen where you can select patients that have been previously added. To add patients follows instructions in 'adding a patient profile' section of this manual.

2. Here you can select up to 10 patients to test simply by pressing their name slot. Selected patients will change from pink to green when selected, to deselect them press the name slot again and it will return to pink.

3. Once the desired patients have been selected, press at the bottom of the screen to progress to the protocol screen.

4. Here you are asked to select the protocol you wish to use for each patient; their name will be shown at the top of the screen. Select the protocol by pressing the protocol name, for example 'lactose', when selected the protocol will change to green. To edit the protocol timings please see 'edit testing Protocols' section of this manual.

5. Press at the bottom of the screen to progress to the next patient.

6. When the final protocol has been selected and when selecting a patient during testing, you will be presented by three options for the first patient. Their name will be shown at the top of the screen.

7. To perform a breath test (please note: if this is the base sample no substrate/sugar should be given to patient before this point) press and follow steps 4-8 of the 'taking a breath test' section of this manual.

8. To perform a face mask test (please note: if this is the base sample no substrate/sugar should be given to patient before this point) press and follow steps 3-6 of the 'taking a face mask test' section of this manual.

9. If the test is unsuccessful in any way you can take the test again by pressing on the result screen, this will overwrite the previous result.

10. Once you are satisfied with the result you can save this to the patient profile by pressing the .

11. If this is the base sample, once you have saved the result you will be prompted to give the patient the relevant substrate/sugar. Once they have done this press to continue with the next patient, this will also start the next breath test timer for the previous patient.

12. You will then be prompted to test the next patient in the same way.

13. When the final patient has provided a sample and taken the substrate/sugar a screen will show all the patients in the testing session with countdown timings for each patient until their next test.

14. When the timer for a patient reaches zero, an alarm will sound indicating the next test is ready to be taken and the patient name will turn green.

15. Take the next reading for that patient by pressing their name and following steps 6-10.

16. Once each patient has finished their testing protocol, their name slot will turn green and their readings will be saved in their profile.

17. You can see how many tests have been performed and how many are left for any given patient by selecting their name in the session screen and referring .

18. If you are satisfied with the results before the protocol session has finished you can end the session early by selecting their name in the session screen and pressing . You will be asked to confirm the action by pressing again in the next screen.

19. Once the complete patient session has finished all name slots will show as green and you can return to the patient profiles screen in order to view results by pressing .

20. Results can be downloaded to GastroCHART™ for future reference or printing, follow instructions in 'GastroCHART™ software' section of this manual.

Protocol pre-set timings

The Gastro⁺™ Gastrolyzer® is pre-set with testing protocols that follow time intervals recommended by clinical research. These are shown below:

Test	Dosage	Test frequency (minutes)	Samples
Lactose[3]	25g of Lactose in 250ml of water	0, 15, 30, 60, 90, 120	6
Lactulose[2]	10g of Lactulose in 200ml of water	0, 20, 40, 60, 80, 100, 120, 140, 160, 180	10
Fructose[3]	25g of Fructose in 250ml of water	0, 15, 30, 60, 90, 120	6
Sorbitol[3]	12.5g of Sorbitol in 250ml of water	0, 15, 30, 60, 90, 120	6
Xylitol[3]	25g of Xylitol in 250ml of water	0, 15, 30, 60, 90, 120	6
Glucose[3]	50g of glucose in 250ml of water	0, 15, 30, 45, 60	5

Edit protocol timings

The testing protocols timings can be edited with different timings by following these steps:

1. Press on the main screen

2. Press the

3. Select the protocol to be changed; this will change to green when selected

4. Press

5. Select up to 10 time intervals by pressing the interval slot and increasing/decreasing the timing by pressing or . The base sample cannot be changed and will show as 'base', active intervals will show in green.

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6. Once you have finished editing the protocol press to save, you will then go back to the settings screen.

Edit protocol names

The testing protocol names can be edited by following these steps:

1. Press on the main screen
2. Press the
3. Select the protocol to be changed; this will change to green when selected
4. Press
5. Press the protocol name at the top of the screen for example FRUCTOSE
6. Enter the new or preferred protocol name using the keyboard provided
7. Press to save; you will then go back to the previous screen.

Protocol pre-set thresholds

Below is an interpretation table for general guidance on interpreting the H_2 values for supporting a diagnosis of conditions. Other factors through qualified judgement need to be taken in account by looking at the patient history, on-going symptoms and symptoms during test. H_2 readings can be interpreted as positive or negative using the following pre-set thresholds (this is the increase in reading compared to the base sample):

Test	Positive interpretation
Lactose[2, 3]	$H_2 \geq 20$ppm $CH_4 \geq 12$ppm compared to base sample
Lactulose[4]	H_2 & $CH_4 >20$ppm compared to base sample within 90 minutes of lactulose ingestion
Lactulose[2] SIBO*	a) Early increase of at least 20ppm for the sum of the two gases b) Increase ≥ 20ppm corresponding to the appearance of lactulose in the colon
Lactulose[2] IITT**	Fast ≥ 20ppm peak is detected at 60 minutes Normal ≥ 20ppm peak is detected at 80 minutes Slow ≥ 20ppm peak is detected 100 minutes or later
Fructose[2]	$H_2 \geq 20$ppm $CH_4 \geq 12$ppm compared to base sample
Sorbitol[3]	$H_2 \geq 20$ppm compared to base sample
Xylitol[3]	$H_2 \geq 20$ppm compared to base sample
Glucose[3]	$H_2 \geq 10$ppm $CH_4 \geq 10$ppm compared with base sample

*SIBO = Small Intestinal Bacterial Overgrowth
**IITT = Impaired Intestinal Transit Time

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Edit protocol pre-set positive thresholds

The pre-set thresholds can be edited by following these steps:

1. Press on the main screen.

2. Press the .

3. Select the protocol to be changed; this will change to green when selected.

4. Press .

5. Press .

6. Press or to increase and decrease the threshold.

7. Press to save; you will then go back to the settings screen

Technical specification

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

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Safety information and device symbols

Degree of protection against electric shock	Type BF applied part
Type of protection against electric shock	Internally powered equipment
Degree of protection against ingress of liquid	IPXO - 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.
Refer to manual	
Direct current	
CE mark	
Type BF applied part	
Dispose of according to WEEE	
Serial number	SN
Manufacture by and date	
Bedfont® logo	

## Environment

The Gastro+™ Gastrolyzer® product 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.

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Instrument layout
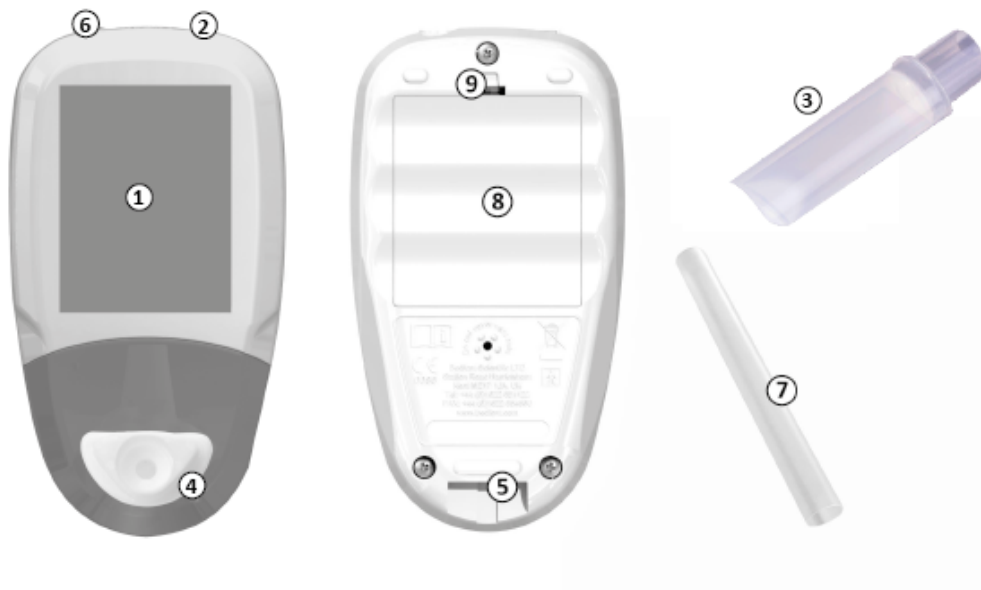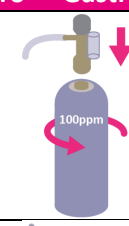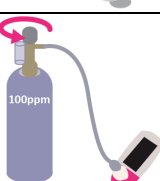
1. Display
2. Power button
3. Breath sampling D-piece™
4. D-piece™ aperture
5. Exhaust port for breath sample
6. USB connector
   (for use with GastroCHART™ software)
7. Single-use SteriBreath™ mouthpiece
8. Battery compartment
9. Battery compartment clip
10. Reset button
11. Programming switch

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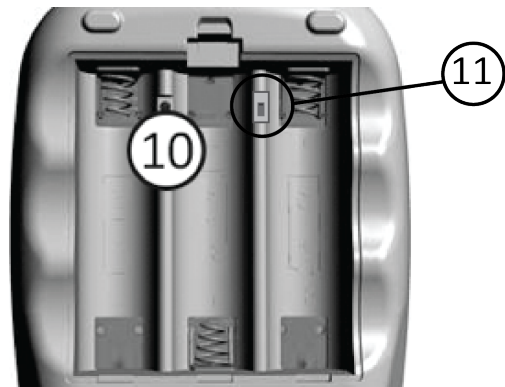
Display symbols

Description	Gastro$^+$™ Gastrolyzer®
Battery condition: full	
Battery condition: low	
Battery condition: empty	
Breath test	
Face mask test	
Automatic patient breath test	
Inhale	
Hold breath	
Edit countdown (breath hold) timer	
Countdown (breath hold)	15
Exhale	
ppm reading	15 ppm H$_2$
Save	
Settings	
Home	

Description	Gastro⁺™ Gastrolyzer®
Patient profiles	
Patient profile slot	1
Patient results chart	
Delete patient record	
Time until next breath sample	00:00 16:09 20:00
Finish and save	 0/6
Change D-piece™	
Next step	
Previous step	
Sensor change due soon	SEN01 15/03/20
Sensor change overdue	SEN01 15/03/20
Calibration due date	12/03/2015
Calibrate device	

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Description	Gastro⁺™ Gastrolyzer®
Attach flow meter to gas canister	
Attach calibration adaptor to D-piece™	
Attach D-piece™ to monitor and turn on gas flow	
System processing	
Calibration successful	
Calibration failed	
Retry calibration	
3 month calibration reminder	
Device reading history	
Edit date/time	MAY 9
Firmware version	V2.23
Serial number	SN: HG000001

Warnings and maintenance

1. SteriBreath™ mouthpieces should be replaced after every use.
2. Hands should be washed regularly in accordance with infection control practice.
3. 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.
4. Bedfont® will make available upon request service training to appropriately qualified persons.

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5. Holding the reset button down for 30 seconds will perform complete device reset, **this will clear any saved data and revert all settings to the factory defaults**. After performing a reset the device will need to have the date/time set and be calibrated before it can be used.

Cleaning

1. The Gastro+™ Gastrolyzer® is moulded with SteriTouch® technology for optimum infection control and has proven bacterial protection efficacy. However Bedfont® recommend wiping the instrument and D-piece™ external surfaces with a product specifically developed for this purpose. Bedfont® provides instrument cleaning wipes. The D-piece™ cannot be sterilised.
2. NEVER use alcohol or cleaning agents containing alcohol or other organic solvents as long term exposure to these vapours will damage the H_2 sensor inside.
3. Under no circumstances should the instrument be immersed in liquid or splashed with liquid.

Reviewing history

The Gastro+™ Gastrolyzer® will record every reading taken in its history up to 150 readings, to access this press ⚙ and then 📖 the history will then be shown.

Changing date and time

Press ⚙ and then 📅 you can then select either d-m-y or m-d-y for the date format and 12h or 24h for the time format. Dates and times are then adjusted by selecting the number you wish to change and pressing ▼ or ▲ to increase and decrease. Press 💾 to save your settings.

Routine maintenance

1. Replace batteries when indicated by the empty symbol 🔋.
2. Bedfont® recommend removal of the batteries when the device is not used for prolonged periods of time to prevent leakage.
3. Replace breath sampling D-piece™ every 30 days or if visibly soiled or contaminated. The Gastro+™ will give a reminder during start-up when the D-piece™ should be replaced, see 'change D-piece™' symbol.
4. The device must be calibrated once every 3 months with a Bedfont® supplied calibration kit and associated gas, see 'calibration'.
5. Bedfont® recommend an annual service in order to check sensor and component parts performance.
6. The sensor should be replaced every two years.

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7. The monitor will provide daily reminders, via the reminder screen 15/03/20, after turning on the Gastro⁺™ for 2 months leading up to the sensor change due date.

8. Additional technical information can be made available on request; please contact Bedfont® or its distributor.

Calibration

The Gastro⁺™ Gastrolyzer® is calibrated at 21°C (±4°C) before leaving Bedfont®. The instrument should be calibrated at 21°C (±4°C) as this is the temperature at which we recommend it is to be used. The Gastro⁺™ Gastrolyzer® should be calibrated every three months and will give a reminder during start-up when calibration is due. The calibration gas required is 100ppm hydrogen in air.

1. Turn on the monitor by pressing the power button once.

2. Press .

3. Start the calibration process by pressing .

4. First the monitor must be zeroed and this will happen automatically, showing this symbol once the calibration process has started, **do not connect gas at this stage.**

5. Once this has been successfully carried out the first step of the calibration process will be shown onscreen. Follow the onscreen instructions to finish the calibration process.

6. Gas flow should be set to 0.5 litres per minute.

7. A successful calibration will be indicated by the , press to return to the home screen.

8. A failed calibration will be indicated by , press to attempt calibration again. If the problem persists see 'troubleshooting' or call your local supplier of Bedfont® products.

9. Return to the home screen by pressing .

Troubleshooting

If the unit fails to turn on properly, check if the low or empty battery symbols are shown or replace the batteries. Ensure that the batteries are inserted the correct way around, matching the symbols moulded into the plastic.

GastroCHART™ software – connecting to the PC

Place one end of the connection lead into the USB socket on the top of the Gastro⁺™ Gastrolyzer®, connecting the other end to the USB port on the PC. Before starting the software, ensure that the Gastro⁺™ Gastrolyzer® is connected to the PC and switched on. Double click the GastroCHART™ icon on the PC to start the programme. Refer to the supplied documentation for how to operate GastroCHART™. (GastroCHART™ available to download for FREE at www.Bedfont®.com)

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Returns procedure

If your equipment requires servicing, please contact your local Bedfont® Customer Service Department, distributor or supplier before returning any goods.

1. When you have supplied the customer repairs department with the monitor serial number and description of the fault, you will be issued with a returns/ ticket number. Please state the returns/ticket number on the outside of the box when returning the monitor, and ensure that your full details, telephone, fax numbers and return address are clearly stated.

2. The product must also be decontaminated before it is returned according to your local regulations. Bedfont® can provide you with a decontamination certificate to complete, which also needs to be attached to the outside of the box. Failure to do so will result in the product being subject to Bedfont® decontamination procedure and will delay your service/repair and may incur costs to yourself.

3. Bedfont® advises that you use a courier service when returning monitors. This enables you to insure goods for loss or damage in transit. When your goods are received, you will be sent an email stating so.

4. If the device has been returned for repair it will then be examined and you will be sent an 'engineer's report' and a quotation for the repair, which will include an authorisation form. Complete the authorisation form, and ensure that you include the 'official purchase order number'. Please contact the customer repairs department if you are unable to supply an 'official purchase order number'.

5. If your monitor is still in warranty and the fault is covered by warranty, see 'warranty' section of this manual, Bedfont® will repair it and return it to you with an 'engineer's report', free of charge.

6. If you choose not to proceed with the repair, a handling fee will be charged. Ensure that you return the completed authorisation form with an 'official purchase order number'.

7. The equipment will be returned to you as soon as Bedfont® has received all relevant paperwork. A carriage fee will be charged if the monitor is no longer in warranty.

Spares

SteriBreath™ mouthpieces:	SteriBreath™ mouthpieces are both cost effective and compact. They are individually sealed for optimum infection control, whilst condensation in the tube confirms an accurate breath sample.
D-piece™:	The D-piece™ is used to attach a SteriBreath™ mouthpiece to the monitor. The D-piece™ incorporates a one-way valve and an infection control filter, which are proven to remove and trap >99.9% of airborne bacteria[5]. The D-piece™ should be changed every four weeks or more often if visibly soiled. An automatic reminder will appear on the screen every 28 days.
OneBreath™ mouthpieces:	The OneBreath™ mouthpiece is a single-use bacterial filter mouthpiece and can be attached directly to the monitor to take a breath sample. The OneBreath™ incorporates a one-way valve and an infection control filter, which are proven to remove and trap >99.9% of airborne bacteria[5].

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Face mask sampling system:	This sampling system is single patent use and allows the patient to breathe normally through a face mask in order to produce a breath sample. Also available in adult, adolescent and infant sizes.
Monitor cleaning wipes:	Free from alcohol to ensure continued performance of your monitor. Products containing alcohol cannot be used on any of the Gastrolyzer® range.
Calibration gas	The Gastro^{+}™ requires calibration quarterly using 100ppm H_2 gas, provided as a kit or replacement cylinder.

Warranty

Bedfont® Scientific Limited warrants the Gastro^{+}™ Gastrolyzer® product (excluding batteries and H_2 sensor) to be free of defects in materials and workmanship for a period of two years from the date of shipment. The H_2 sensor is warranted for 12 months. 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® or the local representative.

This warranty is automatically invalidated if the products are repaired; altered, void labels removed or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.

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.

References

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

www.bedfont.com
Tel:+44 (0)1622 851122
Email: ask@bedfont.com

A full list of our worldwide distributors can be found at
http://www.bedfont.com/uk/english/distributors

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