

Micro⁺ Smokerlyzer®

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Operating Manual



breath analysis is the new blood test

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Intended Use

The Micro⁺ Smokerlyzer® is a breath carbon monoxide monitor intended for multi-patient use by healthcare professionals in smoking cessation programmes and as an indicator of carbon monoxide poisoning in a health care environment.

Introduction

Carbon monoxide is a toxic, odourless, colourless, tasteless gas. It is formed from incomplete combustion of organic material at high temperatures with an insufficient oxygen supply.

When inhaled, CO competes successfully with oxygen in the bloodstream to form carboxyhaemoglobin (COHb). This starves the body tissues of the oxygen vital to repair, regeneration and general living. CO can remain in the blood stream for up to 24 hours, depending on a range of factors including physical activity, gender and inhalation intensity. The half-life is about 5 hours.

CO (ppm)/carboxyhaemoglobin (%COHb) correlation:

Breath carbon monoxide is measured in parts per million (ppmCO) and blood carboxyhaemoglobin in percentages (%COHb). The two are compatible and convertible, CO relating to lung/breath and COHb to blood gas – the Micro⁺ displays both measurements. Clinical research has demonstrated that a useful relationship between carbon monoxide and carboxyhaemoglobin is obtained by a short period of breath holding by the person.¹ CO readings demonstrate the levels of poisonous inhaled CO while the COHb reading shows the percentage of vital oxygen that has been replaced in the bloodstream.

Smoking status

The cut-off between smoker and non-smoker is likely to be 6ppm CO.² The Micro⁺ uses a coloured traffic light system to motivate the patient to give up smoking. There are a number of clinical studies that have found other cut-off points to determine smoking status. The Micro⁺ is supplied with two set profiles and the ability for the user to set additional profiles.

These profile settings are designed to provide motivation to the patient to give up smoking and therefore should only be used as an indication of smoking habit. The different profile settings affect only the colour classification displayed, not the smoker's CO reading.

The Micro⁺ also has the capability to estimate foetal carboxyhaemoglobin (%FCOHb) – the equivalent carboxyhaemoglobin levels present in the foetus in correlation to a pregnant mother's expired CO levels.³ This measurement is not for the diagnosis of CO poisoning but as an indication of the level of CO present in the foetus and is used solely to motivate the mother to give up smoking.

Indication of CO poisoning

If an unexpectedly high reading is displayed, this could indicate CO poisoning. In this case the patient should be referred to the appropriate medical facility for further investigation and treatment.





The %FCOHb is derived by calculation from the patient COppm reading and therefore should not be taken as an indicator of CO poisoning of the foetus. This is used solely to motivate the mother to give up smoking.

¹R. West; Effect of duration of breath holding on expired air carbon monoxide concentration in cigarette smokers; Addictive Behaviours, Vol 9 (1984), 307-309

²E. Middleton, A. Morice; Breath carbon monoxide as an indication of smoking habit; Chest (2000) 117, 758-763

³C. Gomez, I. Berlin, P. Maruis, M. Delcroix; Expired air carbon monoxide concentration in mothers and their spouses above 5ppm is associated with decreased foetal growth; Preventive medicine 40 (2005) 10-15

Warnings

- If an unexpectedly high CO reading is displayed, this could be due to CO poisoning. Seek further medical advice.
- Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the CO sensor inside.
- Under no circumstances should the instrument be immersed in liquid or splashed with liquid.
- People with lung disease or chest ailments may not be able to achieve the breath-hold. In such cases, the user should inhale and hold their breath when the breath test is started, and exhale, if necessary, before the countdown has completed. This may result in a lower reading, but may still provide an indication of a smoking habit.
- During start-up, if the  icon is displayed then calibration is due. Please refer to page 13 for instructions. The unit may give false readings if not calibrated.
- During start-up if the  icon is displayed then the D-piece requires changing. It is recommended that the D-piece is changed every month or earlier if visibly soiled.
- The battery life is indicated by the  icon. When the  icon is displayed the batteries should be changed.
- The disposable cardboard mouthpieces are single-use only as re-use can increase the risk of cross-infection.
- See Bedfont's Infection Control and Maintenance Guidelines for further information on infection control.
- Changing profile settings does not affect the smoker's CO reading, only the traffic light colour classification displayed.
- Care should be taken not to cover the exhaust port of the instrument during a breath test. Labels should never be placed over this outlet.
- The USB port should be used to connect to a PC, in order to run the COdata+ PC software please ensure that the monitor is only connected to a computer that is manufactured in accordance with EN60950.
- Keep the PC out of reach of the patient when the Micro⁺ is connected.

Contraindications

- The sensor has a cross-sensitivity to hydrogen which could affect the CO result. Hydrogen could be present on the breath due to certain gastrointestinal conditions. The sensor also has a cross-sensitivity to nitric oxide and ethylene.
- Temperature may affect the accuracy of the Micro⁺. The instrument should be calibrated at the temperature at which it is expected to be used. If the Micro⁺ is used at a lower temperature than when it was calibrated the readings may be lower. When used at a higher temperature than calibrated the readings may be higher.


Caution

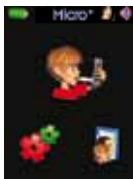
Federal law restricts this device to sale by or on the order of a physician.

Quick Start Guide

- 1 Press the on/off button until the display becomes active. Release the button.

- 2 Insert the D-piece into the instrument and fit a new cardboard mouthpiece.

- 3 Touch the  icon to start a breath test.



- 4 This starts the breath-hold countdown. The patient should inhale deeply and hold their breath while the display counts down to zero. If unable to hold their breath for the full countdown, see Warnings on page 4 or Settings on page 12.

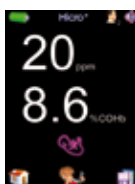



- 5 The audio bleep will sound during the last three seconds of the countdown.

- 6 At end of the countdown, the patient should blow slowly into the mouthpiece, and exhale until their lungs are empty.



- 7 The ppm and %COHb value will rise, and the highest level will hold.




- 8 To view the corresponding %FCOHb, touch the .



- 9 Remove and dispose of the cardboard mouthpiece safely.

- 10 Remove the D-piece between tests to allow fresh air to purge sensor.

- 11 Touch  to perform another breath test. A new mouthpiece is required.

- 12 To switch off, press the on/off button for 3 seconds. Unit will also auto power-off after 5 minutes of inactivity.

Specification

Concentration range:	0-250ppm carbon monoxide (CO)
Mode of Operation:	Continuous
Display:	Colour LCD with 1ppm increments
Detection principle:	Electrochemical sensor
Accuracy (repeatability of readings):	±2ppm or ±2%*
Hydrogen cross-sensitivity:	<±5%
Batteries:	3 × AA (LR6 or equivalent) alkaline batteries
Response time:	Typically <20 seconds to 90% FSD
Operating temperature range:	 0-40°C
Operating humidity:	10-90% non-condensing
Sensor operating life:	2-3 years, 6-month warranty
Sensor sensitivity:	1ppm
Transport/Storage Temperature:	 0-50°C
Transport/Storage Pressure:	800-1200mbar
Transport/Storage Humidity:	15%-90% rh non condensing
Dimensions:	Approx. 44 × 77×138 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



Attention: Consult accompanying documents

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 Micro+ 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.

*Whichever is greater.

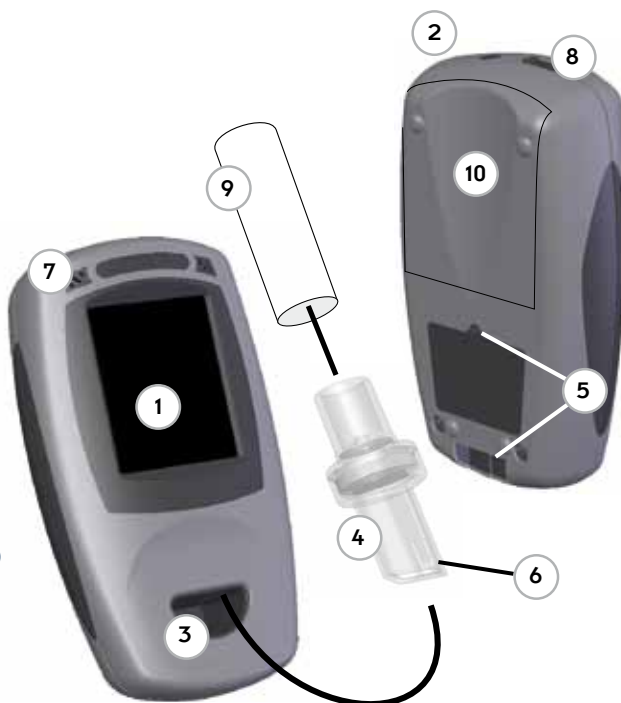
Pack Contents List

- 1 Instrument
 - 2 Operation Instructions
 - 3 Box of D-pieces
 - 4 Disposable Flatpak cardboard mouthpieces
 - 5 3 x AA batteries
- Infection control and maintenance guidelines
- Warranty and registration card
- USB cable
- CD with COdata+ software



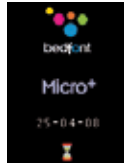
Instrument Layout

- 1 Display
- 2 On/Off switch
- 3 Aperture for D-piece
- 4 Breath sampling D-piece
- 5 Exhaust port for breath sample
- 6 Locating lug on D-piece
- 7 Sounder
- 8 USB Connector (for use with COdata+ PC software)
- 9 Cardboard mouthpiece
- 10 Battery Compartment



Display Symbols

1. Start-up screen:



2. Calibration prompt start-up screen:



3. D-piece 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:



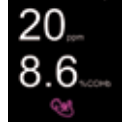
14. Breath-hold and countdown:



15. Exhale for breath test:



16. Peak reading (COppm/%COHb):



17. Display %FCOHb:



18. New breath test:



19. Save breath test:



20. Set instrument zero in fresh air:



21. Apply calibration gas at 50ppm:



22. Calibration/zero: pass



fail



23. Retry calibration/zero:



24. User profile selection:



25. Select adult user profile:



26. Select adolescent user profile:



27. Select custom user profile (if set via COdata+):



28. Breath hold timer setting:



29. Set date/time:



30. System info screen:



31. Contact Bedfont or distributor for help:



Maintenance

Calibrate in accordance with procedure on page 13.

Replace batteries when indicated.

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

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

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

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


Cleaning

Wipe the instrument and external D-piece surfaces with a product specifically developed for this purpose. Bedfont provides an Instrument Cleansing Wipe.


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

Under no circumstances should the instrument be immersed in liquid or splashed with liquid.

Operation

- Ensure 3 AA alkaline batteries are correctly located in battery compartment.
- The touch-screen controls all functions once the instrument is switched on.
- Press the on/off button until the display becomes active. Release the button. After a one-minute warm-up period during which the start-up screen is displayed, the main menu is then displayed.
- If a  and ppm value is shown rather than the main menu, the instrument has failed to set a fresh air zero during start-up. Ensure that the instrument is in fresh air and then touch the screen to repeat the start-up test. If it fails again, please read Troubleshooting page 15.

Note: If the Micro⁺ requires calibration (every 6 months) then the calibration prompt screen will appear, giving the option to calibrate or not.

If the D-piece requires changing (recommended monthly) then the D-piece change prompt screen will appear. Touch  to accept. The reminder will now be reset and will prompt again in 28 days.

- The main menu displays three symbols:

1 Breath test



2 Settings






3 Patient select



Note: The patient select icon will not be accessible until patient data has been downloaded from COdata⁺ and will remain greyed out.




Breath Test










- Attach a D-piece and a new cardboard mouthpiece to the Micro+. Check all connections are pushed firmly together.
- To start a breath test, touch the  icon.

Note: If the display shows  then the sensor has not had time to settle to zero before the test. If this happens, the display will show a  once the sensor has settled and the unit is ready for the test.

- The patient should then inhale as deeply as possible and hold their breath throughout the countdown. The display will show the countdown, and the audio beep will sound during the last three seconds of the countdown.
- Exhale slowly but gently into the mouthpiece. The patient should exhale until their lungs are empty.

Note: If the patient cannot hold their breath for the full countdown, they should commence exhalation at a comfortable point, but exhale completely. See Settings, page 12 and Warnings, page 4.

- The display will show a rising ppm and %COHb value.
- The peak reading will be shown on the display. The test is complete when the    icons are displayed.

- To view the corresponding %FCOHb value, touch the . To go back to the ppm and %COHb reading, touch the  again.
- Remove and dispose of the cardboard mouthpiece safely.
- Removing the D-piece between tests will allow fresh air to purge the unit. It is good practice to wash hands after removing the D-piece.
- To start another breath test, fit a new cardboard mouthpiece and touch the  icon.
- To return to the main menu, touch .
- To save the result to the patient database, press . Select the patient using the  and  arrows and press  to save or  to cancel. Either option will return to the main menu.

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

- If no further tests are required, press the on/off button until the Micro+ turns off. If left on, the Micro+ will automatically turn off after 5 minutes of inactivity.

Description	User Profile 1: Adult (ppm)	User Profile 2: Adolescent (ppm)
Green	0-6	0-4
Amber	7-10	5-6
Red	11-15	7-10
Red	16-25	11-15
Red	26-35	16-25
Red	36-50	26-35
Red	51+	36+


Settings

The settings menu allows access to the following functions:

- Sounder
- User profile
- 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 change from sounder-on to sounder-off (or back again); touch the large  icon in the Settings menu. The large sounder symbol and the small symbol on the top line of the display will change to show whether the sounder is on or off.

Even if the sounder has been turned off, it will continue to operate during the last 3 seconds of the breath-hold countdown.

User Profiles

It is possible to change the profiles between adult and adolescent (or a custom profile if one has been set).




The profiles determine the colour of the background during a breath test. The default values for adults and adolescents are shown in the table on page 11.



To change the selected profile, touch  in the main menu, then touch . Touch  to select the adult profile,  for the adolescent profile or  for the custom profile. The currently selected user profile is indicated by the small symbol on the top line of the display.

The custom profile will only be available if it has been previously set using COdata+.


Breath-hold Countdown Timer

It is possible to change the length of time that the patient should try to hold their breath¹. See Warnings page 4.



Touch  in the Settings menu. Touch  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 done. To change the date and time, touch  in the Settings menu.










Touch the required field and use  or  to change.

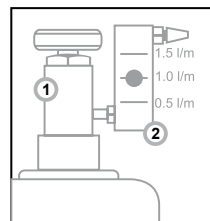
Press  to save or  to cancel. Return to main menu.

System Information

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

Zero/Calibration



- The instrument should be calibrated at the temperature at which it is expected to be used. See Warnings page 4.
- The Micro+ is calibrated at $21 \pm 4^\circ\text{C}$ before leaving Bedfont.
- The Micro+ should be calibrated at 6 monthly intervals. The Micro+ will give a reminder when calibration is due during start-up.
- The calibration gas required is 50ppm carbon monoxide in air.
- Turn the instrument on in the normal way and from the main menu select the Settings menu, then .
- 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.
- Connect calibration apparatus as illustrated.
- Touch  to begin calibration.
- Immediately open the fine control valve by turning the control knob anti-clockwise and allow the gas to flow at 1 litre per minute.
- To maintain this, adjust the flow so the ball in the flow indicator remains on the middle line.
- As the 50ppm CO calibration gas is applied, the displayed ppm reading will climb.
- Monitoring the rate of flow, continue to apply the gas.
- If the final displayed reading is between 45 and 55ppm, the calibration value will be automatically set in the instrument as 50ppm 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 Micro+ is now calibrated and ready for use.





1. Fine control valve
2. Flow indicator



Patient Information














Touch  on the main menu to access patient information, then touch . This icon remains inactive until patient data has been downloaded via COdata+.

Touch  or  to highlight the required patient.

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

Touch  to return to previous menu.

Troubleshooting

- If the unit fails to turn on properly, or if the low battery symbol is showing, replace the 3 x AA alkaline batteries. Ensure that the batteries are inserted the correct way round, 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 touch  to restart the zero process. If, after a third zeroing attempt, the display shows  again, the unit will have to be returned to Bedfont or its distributor for investigation and repair. In this case, the display shows   . The unit can be turned off by holding the on/off button for three seconds. It is possible to re-start the unit and attempt the zeroing process again.
- If, after an attempted calibration with 50ppm CO gas, the display shows , the gas value was not within the permitted limits. The achieved reading is displayed underneath the . If this value is much lower than 50ppm, there may have been a problem with the supply of gas from the cylinder during the calibration process. If the displayed value is much higher than 50ppm, it is possible that the wrong concentration of calibration gas is being used. In either case, check the cylinder, connections and flow-rate before touching  to repeat the gas calibration process. If, after a third repeated attempt to calibrate the instrument, the display shows  again, the unit will have to be returned to Bedfont or its distributor for investigation and repair. In this case, the display shows   . The unit can be turned off by pressing the on/off button. It is possible to re-start the unit and use it with the previous calibration settings, or attempt the complete calibration process again.

Returns Procedure

Should equipment require servicing, please contact Bedfont's Customer Service Specialist before returning any goods. If equipment was not purchased direct 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 this number when returning the monitor, ensuring full details, including telephone and fax numbers, are clearly provided.
- Bedfont advise using a courier service when returning monitors.
- Confirmation will be sent when goods are received.
- An Engineer's Report and a quotation for the repair will be sent following investigation. This includes an Authorisation Form.
- 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 outside of warranty, complete the Authorisation Form within the quotation to proceed with the repair or calibration. Ensure an Official Purchase Order Number is included, and return to Bedfont. Contact the Customer Service Specialist with any queries.
- If it is decided not to proceed with the repair, a handling fee will be charged. Ensure 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:

D-pieces

Disposable Flatpak mouthpieces

Calibration gas and kits

Instrument cleansing wipes

AA alkaline batteries

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 Limited warrants the Micro+ (batteries excepted) to be free of defects in materials and workmanship for a period of two years 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 Limited 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.



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



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