

Operating Manual



breath analysis is the new blood test

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Intended Use

The ToxCO is a breath carbon monoxide monitor intended for multi-patient use by healthcare professionals in a healthcare environment, to determine levels of carbon monoxide (CO) poisoning.

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 bloodstream 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 with no treatment (normal environmental conditions), 1.5 hours if 100% oxygen is given and 0.58 hours if hyperbaric oxygenation at 100% oxygen is given.

Breath carbon monoxide is measured in parts per million (ppm) and blood carboxyhaemoglobin in percentages (%COHb).

The two measurements are compatible and convertible, CO relating to lung/breath and COHb to blood gas. The monitor displays %COHb and ppm using the conversion graph in the appendix on page 19.





COppm 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.

Clinical research has demonstrated that a useful relationship between carbon monoxide and carboxyhaemoglobin is obtained after a short period of breath holding by the person, although this is not essential to assisting in a diagnosis.

Operation of the ToxCO instrument is straightforward. A D-piece sampling system enables end-expired breath to be sampled easily and hygienically, using single-use disposable cardboard mouthpieces. Alternatively, for unwilling or unconscious patients, a facemask can be used.

A colour touch-screen ensures ease of operation, as well as allowing the user to view previous results in a table.

Warnings

- 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, chest ailments or other injuries 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.
- If it is impossible for a breath-hold to be achieved, the facemask and adaptor should be used.
- During start-up, if the  icon is displayed then the calibration is due. Please refer to page 14 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, facemasks and T-piece adapters are single-use only as re-use can increase the risk of cross-infection.

- Tests using the facemask may give a lower reading and therefore a multiplication factor of 1.5 times has been applied to take this into account.
- See Bedford's Infection Control and Maintenance Guidelines for further information on infection control.

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.
- Temperature may affect the accuracy of the ToxCO. The instrument should be calibrated at the temperature at which it is expected to be used. If the ToxCO 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.
- The ToxCO is not to be used as personal protective equipment and is not intended to be a substitute for a personal CO gas alarm. The display values will alert the user to high ambient CO levels. The audible alert is intended to give additional feedback but is not of sufficient volume to be used as an alarm.

Quick Start Guide

- 1 Press the on/off button until the display becomes active. Release the button.
- 2 If a background level of CO >5ppm is detected during start-up, the display shall show the level in ppm. Press  to continue.
- 3 If the patient is conscious, insert the D-piece into the instrument and fit a new cardboard mouthpiece.
- 4 Touch the  icon to start a breath test.
- 5 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 13.
- 6 The audio beep will sound during the last three seconds of the countdown.
- 7 At end of the countdown, the patient should blow slowly into the mouthpiece, aiming to empty their lungs completely.
- 8 The %COHb and ppm value will rise. The highest level will hold and will be stored in the instrument's memory.
- 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 and hold the on/off button for 3 seconds. Unit will also auto power-off after 30 minutes of inactivity.






For tests with unconscious or unwilling patients, or to start an ambient level test, read the instructions on page 12.

Pack Contents List

- 1 Instrument
 - 2 Operation instructions
 - 3 Box of D-pieces
 - 4 Box of disposable cardboard mouthpieces
 - 5 T-piece facemask adapter
 - 6 Infant facemask
 - 7 Child facemask
 - 8 Adult facemask
 - 9 6 x AA batteries
- Infection control and maintenance guidelines
Warranty registration card



Specification

Concentration range:	0-50%COHb / 0-500ppm
Display:	Colour LCD with touch screen
Detection principle:	Electrochemical sensor
Accuracy (repeatability of readings):	± 5% of full scale
Hydrogen cross-sensitivity:	<5%
Batteries:	3 x AA (LR6 or equivalent) alkaline batteries
Response time:	Typically <20 seconds to 90% FSD
Operating temperature range:	 0-40°C (Storage 0-50°C)
Operating humidity:	 10-90% (Storage 0-95%) 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 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



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 ToxCO 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.

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 Flatpak mouthpiece
- 10 Battery Compartment
- 11 T-piece adapter
- 12 Facemask

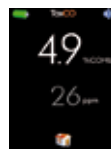


Display Symbols

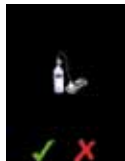
1. Start-up screen:



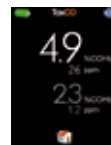
15. Peak reading (%COHb / COppm):



2. Calibration prompt start-up screen:



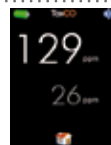
16. Peak and real-time facemask reading (%COHb / COppm):



3. D-piece prompt start-up screen:



17. Peak and real-time ambient air reading (COppm):



4. Battery condition:



18. Set instrument zero in fresh air:



5. Sounder:

on



off



19. Apply calibration gas at 50ppm:



6. Return to main menu:



20. Zero/calibration:

pass



fail



7. Start breath test:



21. Retry zero/calibration:



8. Start facemask breath test:



22. Breath-hold timer setting:



9. Start ambient air test:



23. Set date/time:



10. Settings:



24. System info screen:



11. Patient data:



12. Inhale:



25. Contact Bedfont or distributor for help:



13. Breath-hold and countdown:



14. Exhale for breath test:



Maintenance

Calibrate in accordance with procedure on page 14.

Replace batteries when indicated.

Replace D-piece every month or if visibly soiled or contaminated. It cannot be cleaned or sterilised. The ToxCO 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 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. The start-up screen will be displayed for a 15 second warm-up period, followed by the main menu.

Note: If the ToxCO 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.


- If a background level of CO >5ppm is detected during start-up, the display shall show the level in ppm. Press  to continue.
- The main menu displays three large symbols and two small symbols:
 - 1 Breath test 
 - 2 Facemask test 
 - 3 Ambient air test 
 - 4 Settings 
 - 5 Stored readings 

Breath Test – Conscious and Willing Patients



- Attach a D-piece and a new cardboard mouthpiece to the ToxCO. Check all connections are pushed firmly together.
- To start a breath test, touch the  icon.
- 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, aiming to empty the lungs as far as possible.

Note: If the patient cannot hold their breath for the full countdown, they should commence exhalation at a comfortable point, but exhale completely. See timer settings, page 13 and Warnings, page 4.

- The display will show a rising %COHb and ppm value.
- The peak reading will be shown on the display. The test is complete when the  icon is displayed. The peak reading will be saved automatically.
- 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 your 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 .
- If no further tests are required, press and hold the on/off button for 3 seconds then release to turn off. If left on, the ToxCO will automatically turn off after 30 minutes of inactivity.

Facemask Breath Test

- Attach the T-piece adapter and relevant sized facemask.
- To start the test, touch the  icon.
- Apply the facemask to the mouth and nose of the patient, ensuring that they can breathe through it freely.
- The display shows two sets of readings. The top set of white digits represent the peak reading in %COHb and ppm since the test started. The lower set of grey digits show the actual reading in real-time, updated once per second.
- Press the  icon to stop the test and return to the start menu. The peak reading will be saved automatically.
- If the instrument is left in the facemask test mode, the display will reduce to low brightness after one minute of inactivity to save battery power. Tapping any part of the display will restore the screen to its full brightness.
- If left on, the ToxCO will automatically turn off after 30 minutes of inactivity. Tapping the display resets the 30 minute timer.
- If no further tests are required, press and hold the on/off button for 3 seconds then release to turn off. If left on, the ToxCO will automatically turn off after 30 minutes of inactivity.

Ambient Test

The ToxCO instrument has a third operating mode for monitoring the ambient level of carbon monoxide in the air surrounding the instrument.

- Remove the D-piece.
- To start an ambient test press the  icon.
- The display shows two readings. The top, large white numerals, show the peak reading in ppm since the test was started. The lower, smaller grey numerals, show the actual reading in real-time, updated once per second.
- Alert thresholds (see Warnings, page 4) are set as follows:
 - 0-9ppm** - no audible alert with green display digits.
 - 10ppm** - WHO recommended ambient exposure (not workplace). 1 short bleep every 2 seconds, with amber display digits.
 - 30ppm** - HSE EH40 - LTEL. 2 short bleeps every 2 seconds, with red display digits.
 - 200ppm** - HSE EH40 STEL. 3 short bleeps every 2 seconds, with red display digits.
- The display can be left in this mode, but the display will reduce to low brightness to save battery power after one minute of inactivity. Tapping any part of the display will restore the screen to full brightness.
- If left on, the ToxCO will automatically turn off after 30 minutes of inactivity. Tapping the display resets the 30 minute timer.
- Press the  icon to stop the test and return to the main menu. The peak reading will be saved automatically.
- If no further tests are required, press and hold the on/off button for 3 seconds then release to turn off.


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 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.




Breath-hold Countdown Timer



It is possible to change the length of time that the patient should try to hold their breath.

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 carried out. 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

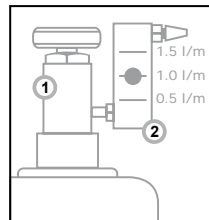
Touch  to access system information such as software version. Touch  to return to the main menu.

Zero/Calibration




- Temperature may affect the accuracy of the ToxCO. See Warnings, page 4.
- The ToxCO is calibrated before leaving Bedfont.
- The ToxCO should be calibrated at 6 monthly intervals. The ToxCO will give a reminder when calibration is due during start-up.
- The calibration gas required is 50ppm carbon monoxide in air. The ToxCO should be calibrated at a flow rate of 1 litre per minute.
- 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 16 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.



1. Fine control valve
2. Flow indicator

- 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 50ppm, 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 16 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 ToxCO is now calibrated and ready for use.

Stored Readings

Touch the  icon to display the stored peak readings from the 20 most recent tests. The results are displayed on four pages, with the most recent test results at the top. Use  or  to scroll to the other pages.

Each page displays five results, with time and date in the first column, peak reading in the second column and the icon representing the type of test in the third column. Results of breath tests with mouthpieces or facemasks will be displayed in %COHb, while ambient test results are displayed in ppm.




Breath test
















Facemask test



Ambient air test

Press the  icon to return to the main 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 Bedford 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 3 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 Bedford 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 3 seconds. 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

D-pieces

Disposable Flatpak mouthpieces

T-piece facemask adapters

Infant, child and adult facemasks

Calibration gas and kits

Instrument cleansing wipes

AA alkaline batteries

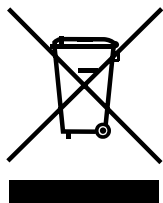
The above spares are available from Bedfont Scientific Ltd, UK. For spares availability in all other countries contact your local distributor. It is recommended that only Bedfont consumables are used.

Warranty

Bedfont Scientific Limited warrants the ToxCO (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.

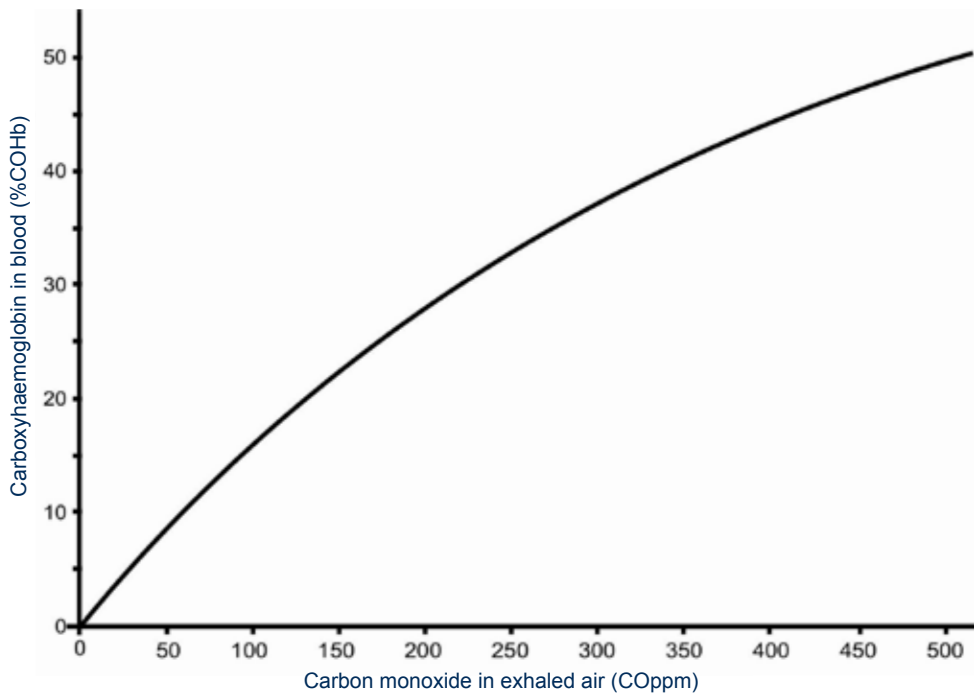
These warranties are automatically invalidated if the products are repaired, altered or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.



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.

Appendix: Correlation Graph

The graph below shows the correlation between carbon monoxide concentrations in expired air (COppm) and blood carboxyhaemoglobin (%COHb) for a fire victim¹.



¹Richard D.Stewart MD, R.Scot Sterart, William Stamm, Richard P.Steelen; Rapid Estimation of Carboxyhaemoglobin Level in Fire Fighters; Journal of American Medical Association; 235:390-392; 1976.



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