

Smokerlyzer[®]

For use with Micro⁺baby



CE
0086

covita[™]
breath analysis is the new blood test

bedfont



Scientific contributions to health.

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Intended Use

The Micro^{+baby™} Smokerlyzer[®] is a breath carbon monoxide monitor intended for multi-patient use by healthcare professionals in smoking cessation programmes and research. They can also be used as an indicator of carbon monoxide poisoning in a healthcare environment.

Introduction




Carbon monoxide (CO) is a toxic, odourless, colourless and tasteless gas. It is formed by the incomplete combustion of organic material at high temperatures, with an insufficient oxygen supply. When inhaled, CO displaces oxygen in the bloodstream to form carboxyhaemoglobin (COHb). This starves body tissue of oxygen restricting the body's performance and causing health implications. CO can remain in the bloodstream for up to 24 hours, depending on factors such as physical activity, sex, and inhalation intensity. The half-life is about 5 hours.







CO (ppm), carboxyhaemoglobin (%COHb) and foetal carboxyhaemoglobin (%fCOHb) correlation: Breath carbon monoxide is measured in parts per million (ppm) and blood carboxyhaemoglobin is measured in percentages (%COHb and %fCOHb). The three are compatible and convertible: the ppm CO reading relates to gas in the lungs and on the breath (i.e. the amount of poisonous CO that has been inhaled), and the %COHb and %fCOHb readings relate to the percentage of vital oxygen that has been replaced in the bloodstream.

The Micro^{+baby™} Smokerlyzer[®] displays CO ppm, %COHb and %fCOHb. However all devices only directly measure CO ppm, the %COHb and %fCOHb is a calculation based on clinical evidence. Clinical research has demonstrated that a useful relationship between carbon monoxide and carboxyhaemoglobin is obtained after a short period of breath-holding.



The cut-off point between smoker and non-smoker differs based on local regulation, Bedfont have created cut-off levels as a guide only, see 'Traffic Light Pre-set Cut off Levels', these can be altered in-line with your local regulations from the settings screen.

Taking a breath test



1. Attach a breath sampling D-piece and new mouthpiece.
2. Turn on the monitor by pressing the power button once.
3. Press 'Breath Test' symbol on screen,  or .
4. To cancel the breath test, press .
5. Inhale and hold breath for the pre-set 15 second countdown.
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 and equivalent %COHb levels will rise and hold on-screen.

9. When the test is finished    will appear at the bottom of the screen.
10. If a high reading has been recorded, you can mute the sound by pressing .
11. To repeat breath test, press  once to return to the home screen and repeat steps 3-8.
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.
14. To switch off, press and hold the power button for 3 seconds, unit will also power off after 2 minutes of inactivity to save power.






Converting %COHb to %FCOHb –

On the readings screen press  to show %FCOHb, press  again to return to the readings screen.

Reviewing history


The Micro^{+baby™} 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.

Traffic Light Pre-set Cut-Off Levels




Traffic light color	Description	Reading (ppm)	Pregnant Smokers Reading (ppm)*
Green	Non-Smoker	0-6	0-3
Amber	Borderline	7-9	4-6
1 Red	Smoker – Low addicted	10-15	7-10
2 Red	Smoker – Moderately addicted	16-25	11-15
3 Red	Smoker – Heavily addicted	26-35	16-25
3 Red Flashing	Smoker – Very heavy addicted	36+	26+

To adjust the pre-set cut off levels, press  from the settings menu and drag the cut off levels up and down to the desired ppm level. These settings will remain until adjusted again.

Technical Specification

	Micro+™baby
Concentration Range (CO)	0-150ppm
Display	Full color touchscreen
Detection Principle	Electrochemical sensor
Repeatability	<±5% on consecutive readings
H ₂ Cross Interference	≤6%
Power	
3 x AA (LR6 or Equivalent)	1 x CR2032 Lithium coin cell
Approx. 3 x AA Battery Life	1,000 uses on new alkaline batteries (approx. 3 min per use)
Approx. 1 x CR2032 Battery Life	175,000 hours
T ₉₀ Response Time	≤30 seconds
Operating Temperature Range	15-40°C (storage 0-50°C)
Operating/Transport/Storage Pressure	800-1200mbar
Operating Humidity	15-90%non-condensing (storage 0-95%)
Sensor Operating Life	5 years – 5 year warranty
Sensor Sensitivity	1ppm
Sensor Drift	<5% per annum
Dimensions	Approx. 34 x 75 x 140 mm
Weight	Approx. 200g (including batteries)
Monitor Construction	Case: Polycarbonate/ABS blend SteriTouch anti-Microbial additive D-Piece: Polypropylene

Safety Information and Device Symbols

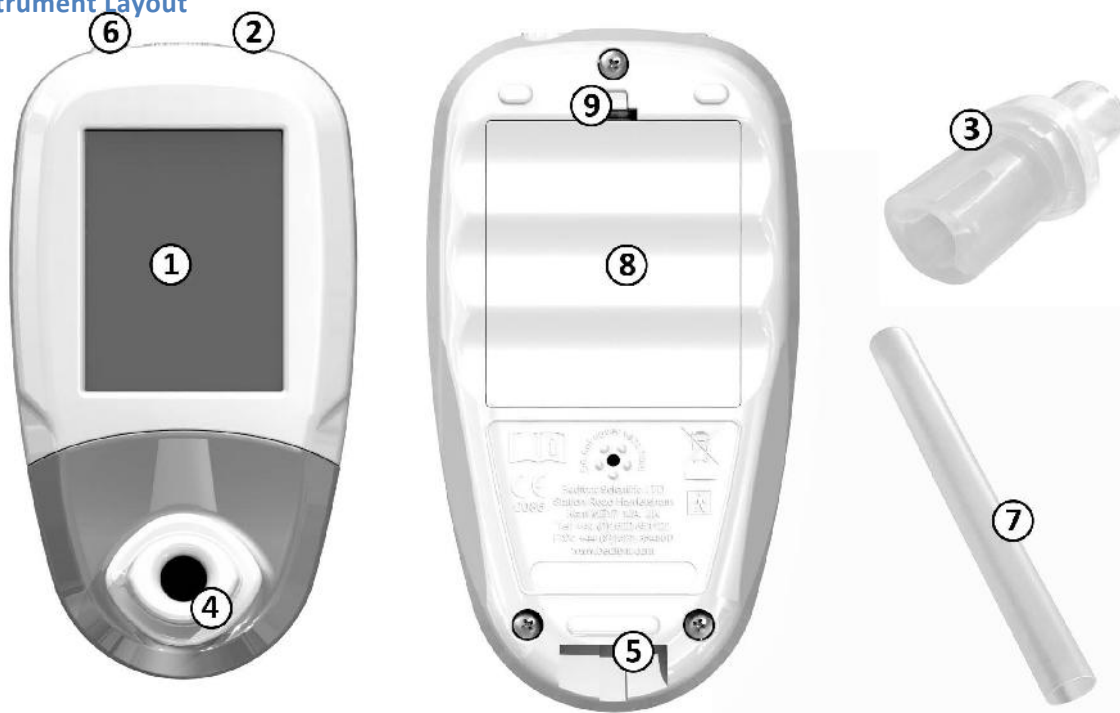
Degree of protection against electric shock	Type BF applied part
Type of protection against electric shock	Internally powered equipment
Degree of protection against ingress of liquid	IPX0 - not protected against water ingress
Degree of safety application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable for use in the presence of flammable mixtures.
Refer to Manual	
Direct Current	
CE Mark	

Type BF applied part	
Dispose of according to WEEE	
Serial Number	
Manufacture by and Date	
Bedfont Logo	

Environment

The Micro^{+baby}™ Smokerlyzer® 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.








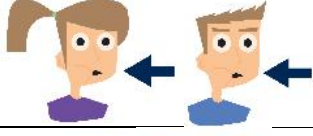
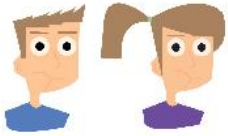

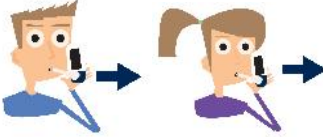


Instrument Layout























1. Display
2. Power button
3. Breath sampling D-Piece™
4. D-Piece™ aperture
5. Exhaust port for breath sample
6. USB connector (for use with COdata Software)
7. Single-use SteriBreath™ mouthpiece
8. Battery compartment
9. Battery compartment clip
10. Reset button



Display and Device Symbols

Description	Micro+baby™
Battery condition: Full	
Battery condition: Low	
Battery condition: Empty	
Breath Test	
Environmental Test	
Settings	
Patient Profiles	
View patient results	
Inhale	
Hold Breath	
Countdown Timer	
Exhale	
ppm Reading	20 ppm CO
%COHb Reading	3.83 %COHb
Show %fCOHb	
%fCOHb Reading	3.83 %fCOHb 

Description	Micro+baby™
Ambient CO reading	
Home	
Change D-Piece	
Change Traffic Light Cut-off Levels	
Save	
Change Breath Hold Time	
History	
Mute	
Change date/time	
Next Step	
Countdown to Sensor Change	 15/03/20
Change Sensor	 15/03/20
Calibrate Device	
Attach Flow Meter to Gas Canister	

Description	Micro+baby™
Attach Calibration Adaptor to D-Piece	
Attach D-Piece to monitor and Turn on Gas Flow	
Unit Calibrating	
Calibration Successful	
Calibration Failed	
Retry Calibration	
Firmware Version	Vers 2.0.1
6 Month Calibration Reminder	

N/A = Not Available on this device






Warnings and Maintenance

1. 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.
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 Smokerlyzer® products are moulded with SteriTouch® technology for optimum infection control and bacterial 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 CO sensor inside.
3. Under no circumstances should the instrument be immersed in liquid or splashed with liquid.

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 Micro^{+baby}™ Smokerlyzer® will give a reminder during start-up when the D-piece should be replaced, see 'Change D-Piece' symbol.
4. The sensor should be replaced every 5 years, 60 days prior to the sensor change 'Countdown to sensor change' symbol will be shown with the date on which the sensor should be changed. This can be ignored by pressing  until the date at which the sensor should be changed arrives, at this point the 'Change Sensor' symbol will be shown. Change sensor if trained to by an approved Bedfont engineer or send to Bedfont or the local representative.
5. Additional technical information can be made available on request; please contact Bedfont or its distributor.
6. The Micro^{+baby}™ Smokerlyzer® requires calibration every 6 months this will be indicated by  press the  and follow instructions to calibrate the device or press  to ignore.

Troubleshooting

The unit fails to turn on:

If the unit fails to turn on, replace the batteries. Ensure that the batteries are inserted the correct way around, matching the symbols moulded into the plastic.

High readings recorded for reported non-smoker:



If a breath test on a non-smoker gives an indication of CO being present, it may indicate the following:



1. A high ambient level of CO (possibly due to a faulty combustion appliance or exhaust fumes).
2. The effects of passive smoking.
3. The device is contaminated by alcohol or another organic substance.
4. The patient may have a very high level of hydrogen on their breath, which can be generated in the human digestive system.
5. The sensor may have drifted out of specification (see below).

The sensor has drifted out of specification:











Smokerlyzer® products are calibrated before leaving coVita, however we recommend if you suspect the instrument is reading incorrectly, try the test again with another device if available to get a comparison. Alternatively you check the function using coVita check gas or send back to coVita. The check gas required is coVita 20ppm carbon monoxide in air, procedure below.

1. Ensure the fine control valve is in the off position.
2. 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.

3. Press 'Breath Test' symbol on screen,  or , to start a breath test.

4. When prompted by the 'Exhale' symbol,  or , open the fine control valve or regulator and allow the gas to flow at 1 litre per minute.
5. Allow the gas to flow through the instrument for the duration of the test, again monitoring the rate of flow.
6. If the final displayed value is less than 18ppm or higher than 22ppm, stop the test and perform a calibration or send back to coVita for an evaluation.

Calibration Procedure

1. Turn on the monitor by pressing the power button once
2. Press 
3. Start the calibration process, pressing the  symbol 5 times and then  once to proceed
4. If the temperature of the monitor is too low to calibrate, the blue thermometer will be shown . Try again later once the unit has warmed up – if this problem persists please contact Bedfont® or your local supplier.
5. If the temperature of the monitor is too high to calibrate, the red thermometer will be shown . Try again later once the unit has cooled down – if this problem persists please contact Bedfont® or your local supplier.
6. Once this has been successfully carried out the device will perform a zero; **do not apply gas at this stage**
7. The first step of the calibration process will be shown onscreen; follow the onscreen instructions to finish the calibration process
8. **Gas flow should be set to 1.0 litres per minute**
9. A successful calibration will be indicated by the , press  to return to the home screen
10. 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
11. Return to the home screen by pressing 

COdata+™ Software – connecting to the PC

Place one end of the connection lead into the USB socket on the top of the Smokerlyzer® product, connecting the other end to the USB port on the PC. Before starting the software, ensure that the Smokerlyzer® product is connected to the PC and switched on. Double click the COdata+™ icon on the PC to start the programme. Refer to the supplied documentation for how to operate COdata+™.

Returns Procedure

If your equipment requires servicing, please contact coVita Customer Service Department, 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.
3. coVita advise 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, coVita will repair it and return it to you with an 'Engineer's Report', free of charge plus shipping and handling..
6. If you choose not to proceed with the repair, a handling fee will be charged. Ensure that you return the completed authorization form with an 'Official Purchase Order Number'.
7. The equipment will be returned to you as soon as coVita has received all relevant paperwork. A carriage fee will be charged if the monitor is no longer in warranty.

Spares

D-PIECE	Box of 12 D-Pieces (non-sterile)
STERIBREATH	Box of 250 SteriBreath Mouthpieces (non-sterile)
WIPES	Pack of 50 Cleaning Wipes
USB-3F	USB Cable

Warranty

coVita warrants the Micro^{+baby™} Smokerlyzer® (excluding batteries) to be free of defects in materials and workmanship for a period of five years from the date of shipment. coVita'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 coVita. These warranties are 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 coVita for trade in credit and/or disposal instructions.

bedfont[®]
est. 1976

coVita[™]
breath analysis is the new blood test

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Rx Only



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