Smokerlyzer® Range

For use with piCO™, piCO^babyTM and Micro^+TM

User manual

$C\epsilon$
2797

Our family, innovating health, for yours. bedfont® est. 1976

Definitions

WARNING: indicates a potentially hazardous situation, which, if not avoided, may result minor or moderate injury.

CAUTION: indicates a potentially hazardous situation, which, if not avoided, may result in damage to the device.

NOTE: used to call attention to notable information that should be followed during use.

Important Information/Reminders

WARNING: Please read the manual before use.

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

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

WARNING: Breath tests must only be carried out with Bedfont® accessories. Failure to do so may cause incorrect readings.

WARNING: The mouthpieces are single patient use only and can be used for a maximum of 3 tests. Further re-use could cause incorrect readings and could increase the risk of cross infection. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.

WARNING: Patients should exhale for the duration of time indicated by the device during a breath test. Failure to do so may cause incorrect readings.

WARNING: To ensure a breath sample is taken at the correct flow rate, the device must be held upright at all times during a breath test.

WARNING: Do not block the exhaust ports on the device at any time. Blocking the exhaust ports may cause erroneous readings.

CAUTION: Ensure the device is used within the stated operating temperature and humidity ranges. Operating temperature is 15-40°C. Operating humidity is 15-90% RH (non-condensing).

CAUTION: Portable and mobile RF communications equipment can affect the Smokerlyzer® devices.

NOTE: See Bedfont's infection control and maintenance guidelines for further information on infection control.

NOTE: 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.

NOTE: Bedfont® will make available on request service training to appropriately qualified personnel.

Contents

Introduction

The User Manual provides instructions on how to operate the Micro⁺™, piCO™, and piCO^baby™ Smokerlyzer® devices and their accessories. It contains relevant information about the devices, their uses and their care, including step-by-step instructions with screens and illustrations.

The piCO™ Smokerlyzer® displays both CO ppm and %COHb, the piCO^baby™ Smokerlyzer® displays both CO ppm, %FCOHb and %COHb, and the Micro⁺™ 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.

Compliance

The Micro⁺™, piCO™, and piCO^baby™ Smokerlyzer® devices are CE marked according to the Medical Device Directive 93/42/EEC as amended by 2007/42/EC.

Please refer to the 'Safety Information' section of this manual for more information on the compliance of the Smokerlyzer® devices.

Intended Use

The piCO™, piCO^baby™ and Micro⁺™ Smokerlyzer® products are breath carbon monoxide devices 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.

Contraindications

There are no known contraindications.

Instrument Layout

1. Power button	6. Battery compartment
2. USB port (for use with COdata$^+$™ software)	7. Exhaust port
3. Display	8. Manufacturer label
4. D-piece™ aperture	9. Exhaust port
5. Battery compartment clip	10. Reset button
	11. Programming switch

User Interface

Micro⁺™ Smokerlyzer®

Home Screen

1. Battery status
2. Maternity breath test
3. Normal breath test
4. Ambient air test
5. Patient profiles
6. Settings

The information screen displays information about the device and sensor.

User Interface

piCO™ Smokerlyzer®

Home Screen
1. Battery status
2. Breath test
3. Settings
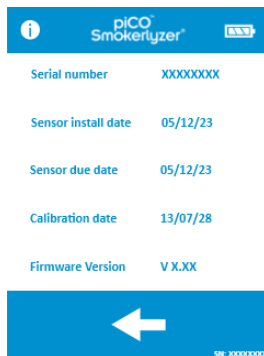
The information screen displays information about the device and sensor.

User Interface

piCO^{baby}™ Smokerlyzer®
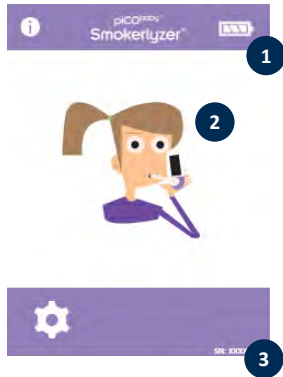
Home Screen

1. Battery status
2. Maternity breath test
3. Settings

The information screen displays information about the device and sensor.

Taking a breath test

Turn on the device by pressing the power button once.

Press the breath test icon on screen, either the male or female symbol.
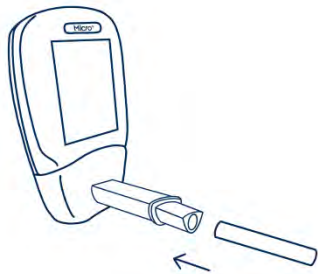
Attach a breath sampling D-piece™ and new SteriBreath™ Eco mouthpiece.

The device may show this screen when the sensor is zeroing.
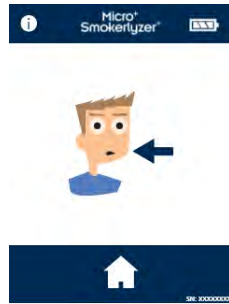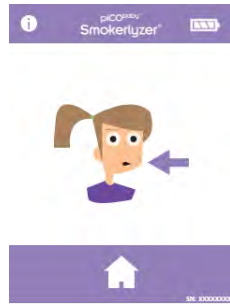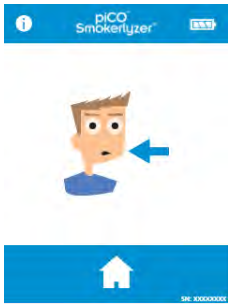
Inhale and hold breath for the pre-set 15 second countdown.

Press the home button at any time to cancel the breath test.
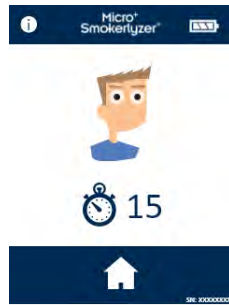
A beep will sound during the last three seconds of the countdown.
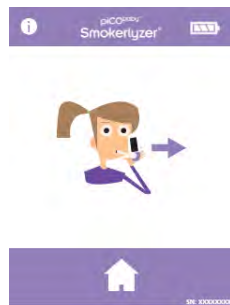
Blow slowly into mouthpiece, aiming to empty lungs completely.
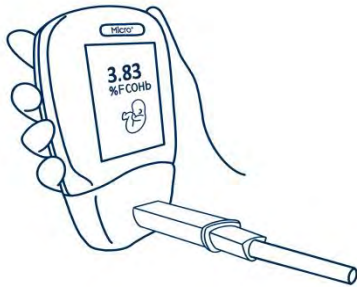
The ppm and equivalent %COHb and/or %FCOHb levels will rise and hold onscreen.
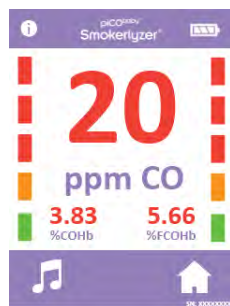
On the piCO™ and piCO^baby™, when the test is finished, the volume and home icons will appear at the bottom of the screen.

On the Micro+™, when the test is finished, the volume, home and save icons will appear at the bottom of the screen.

If a maternity breath test has been completed on the Micro+™, press the foetus icon for the %FCOHb reading.

If a high reading has been recorded, the device can be muted by the sound by pressing the volume icon.

To repeat breath test, press the home icon once to return to the home screen and repeat steps 3-8.

To save the reading (Micro⁺™ only) press the save icon and select the relevant patient profile.

Remove the D-piece™ between tests to purge sensor with fresh air.

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.

Conducting an ambient test – Micro⁺™ only
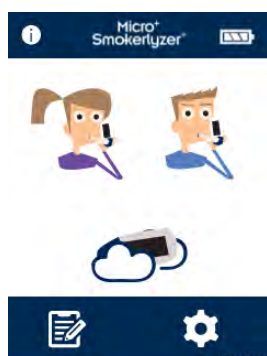
The environmental air can be tested to check for CO in the environment using the Micro⁺™ Smokerlyzer®. This is particularly useful in the event of a patient reporting a non-smoker status but providing a breath reading of that of a smoker suggesting they have inhaled environmental CO.

This is carried out by pressing the ambient mode icon on the screen.

The device may show this screen when the sensor is zeroing.
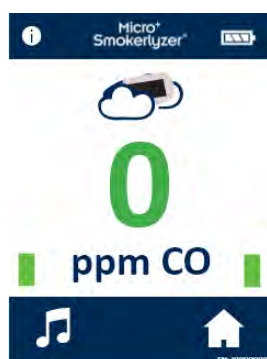
The Micro⁺™ will then carry out real-time monitoring of the environmental air. To stop the test, press the home icon.

Bedfont® does not recommend that the environmental test alone is used as a measure of passive smoking as the very high dispersiveness of CO at the levels involved with smoking can lead to false negative readings.

Patient Profiles – Micro⁺™ only
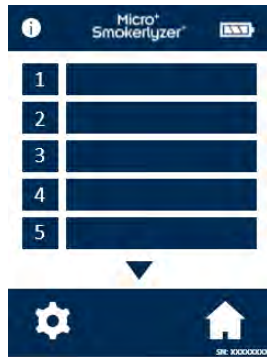
All patient profiles saved on the device will be listed here. To view patient information, press the relevant patient profile block.

To change the name of the patient, press the text box icon.
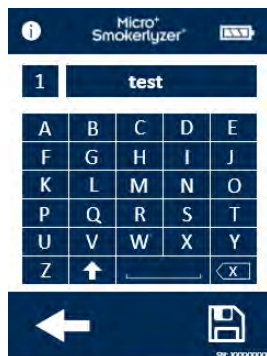
Press the letters required. Click the save icon to confirm or the back arrow to return.
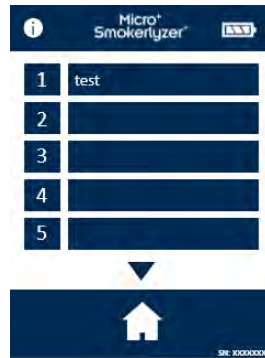
Once the patient profile name has been updated, the name will show when viewing the patient profile screen.

If 'start breath test' is selected from this screen, the breath test will be automatically saved to the profile. Once the type of breath test has been assigned to the patient, only one symbol will appear.
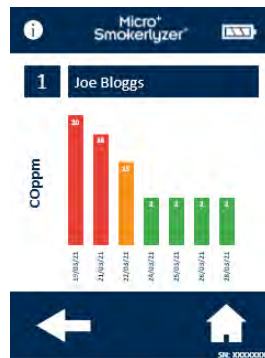
To access the patient's breath test results history, press the graph icon. This will then bring up the patient's testing history.
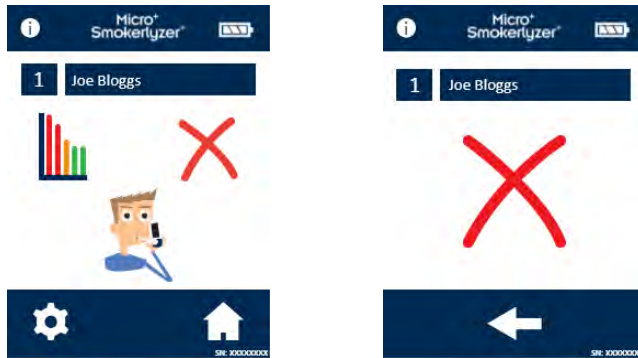
To delete a patient profile, press the delete icon. To confirm, press the delete icon again.
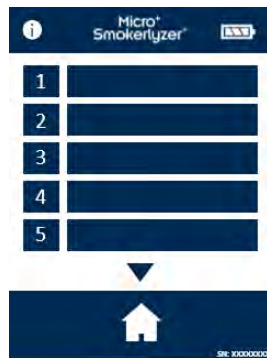
Once confirmed, the patient profile will no longer appear on the patient profile list.

Reviewing history – Micro⁺™ only

Press the settings icon.

Press the history icon.

The Micro⁺™ will record every reading taken in its history up to 150 readings.

Changing date and time – Micro⁺™ only
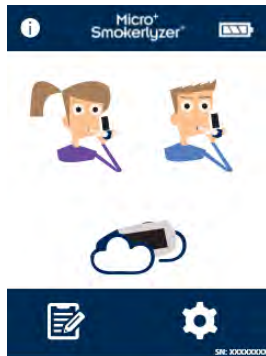
Press the settings icon.

Press the date/time icon.
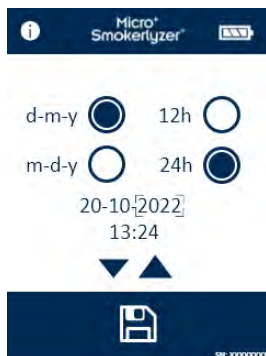
Select either d-m-y or m-d-y for the date format and 12h or 24h for the time format.

Dates and times are then adjusted by selecting the number needing changed and pressing the up or down arrow icons to increase and decrease. Press the save icon to save the new settings.

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Changing breath holding time – Micro⁺™ only
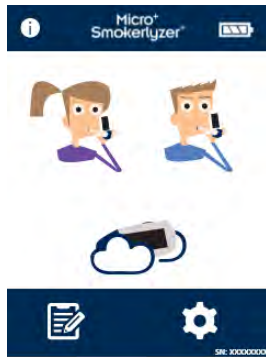
Press the settings icon.
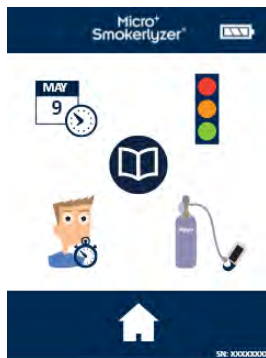
Press the breath holding time icon.

Use the arrows to adjust the breath holding time. Press the save icon to save changes.

Changing breath testing thresholds

Traffic light colour	Description	Reading (ppm)	
		piCO™ & Micro⁺™	piCObaby™
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+

This table shows the pre-set breath testing thresholds.

Press the settings icon.

To change the breath test thresholds, press the traffic light icon.

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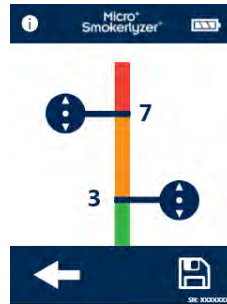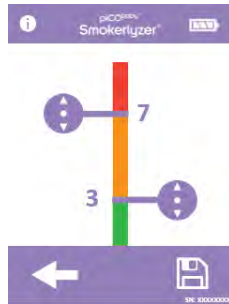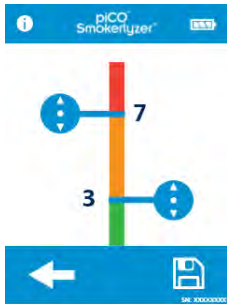
Once adjusted, press the save icon.

Maintenance Reminders
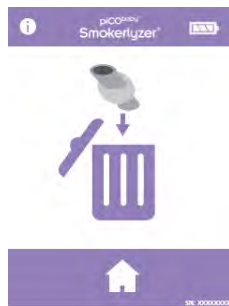
Change D-piece™ reminder

The D-piece™ requires changing every 30 days. This reminder is displayed at switch on.
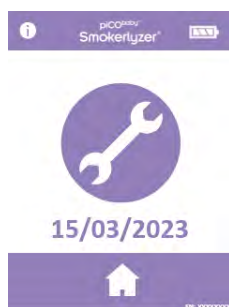
Sensor change reminder

This reminder is displayed at switch on when the sensor is nearing its change date.

After 60 days of this reminder being displayed, the 'red date' alarm takes over.

Sensor change overdue reminder

This reminder is displayed at switch on when the sensor requires replacing.

Press the home icon to begin calibrating the device.

Calibration due reminder

This reminder will display once the home icon on the sensor change overdue screen is pressed. Press the right arrow to proceed to calibration.

This reminder will also be displayed 6 months after calibration is completed, if the sensor has not been changed.

Maintenance

Routine maintenance

1. The mouthpieces are single patient use only and can be used for a maximum of 3 tests.
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.
6. Replace batteries when indicated by the empty symbol.
7. Bedfont® recommend removal of the batteries when the device is not used for prolonged periods of time to prevent leakage.
8. Replace breath sampling D-piece™ every 30 days or if visibly soiled or contaminated. The piCO™, piCO^{baby}™ and Micro$^+$™ Smokerlyzer® products will give a reminder during start-up when the D-piece™ should be replaced, see 'change D-piece™' symbol.
9. 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 the home icon 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 do so by an approved Bedfont® engineer or send to Bedfont® or the local representative.

Cleaning

1. The Smokerlyzer® products are integrated with antimicrobial technology for optimum infection control and bacterial efficacy. Bedfont® recommends wiping the instrument and D-piece™ external surfaces between each patient with an alcohol-free wipe specifically designed for this purpose. A list of approved wipes can be found here: https://www.bedfont.com/cleaning-bedfont-devices. 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.

Calibration

The Smokerlyzer® devices must be calibrated within 17-25°C. If it is too cold to calibrate (<17°C) a blue thermometer will be shown onscreen.

Move the Smokerlyzer® to a warmer area and try again later. If it is too hot to calibrate (>25°C) a red thermometer will be shown onscreen. Move the Smokerlyzer® to a cooler area and try again later.
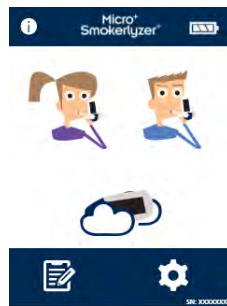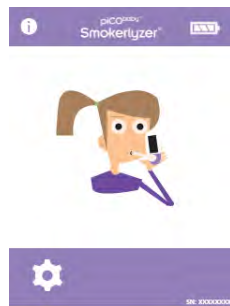
Turn on the device by pressing the power button once.

Press the settings icon.
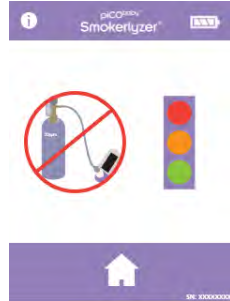
Press the calibration icon 5 times to enable.
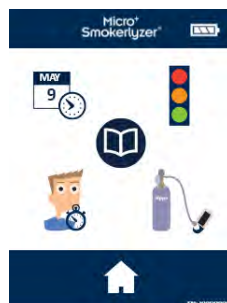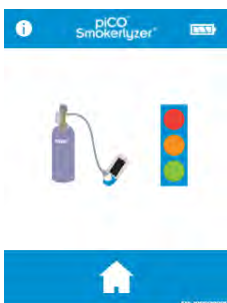
Press the cylinder icon once to proceed.

If the temperature of the device 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 the local supplier.
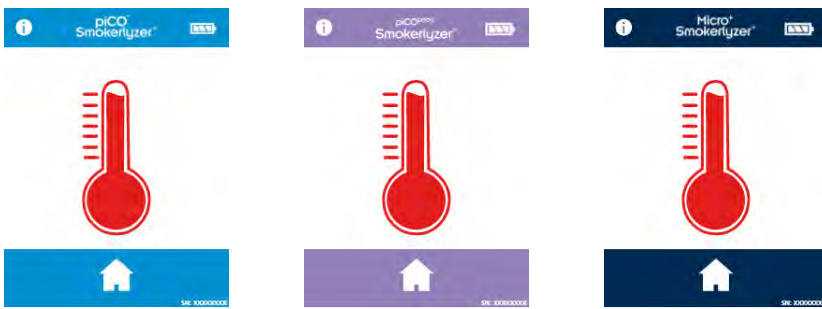
If the temperature of the device is too high to calibrate, the red thermometer will be shown. Try again later once the unit has cooled down – if this problem persists, please contact Bedfont® or the local supplier.

Once this has been successfully carried out the device will perform a zero; do not apply gas at this stage.
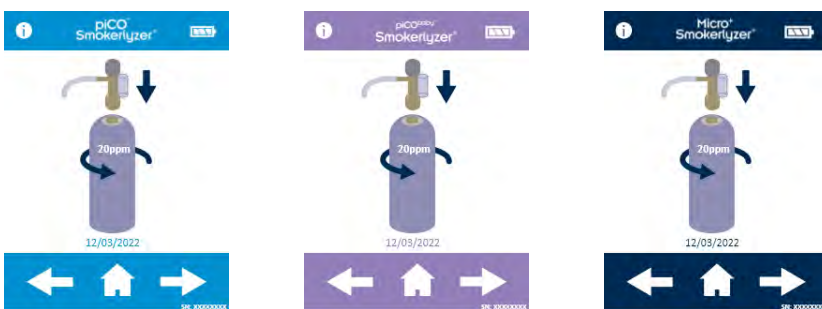
The first step of the calibration process will be shown onscreen; follow the onscreen instructions to finish the calibration process.

Ensure the fine control 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.

Attach a D-piece™ to the calibration adaptor. Press the arrow to continue the calibration process.

Insert a D-piece™ into the device and turn on the gas. Press the arrow to continue.

Allow the gas to flow at 1 litre per minute.

Allow the gas to flow through the instrument for the duration of the test, again monitoring the rate of flow.
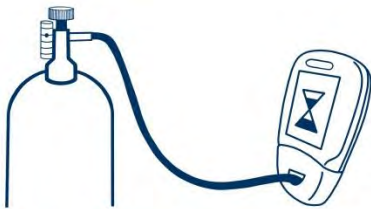
If the final displayed value is less than 15ppm or higher than 25ppm, stop the test and perform a calibration or send back to Bedfont® for a free of charge calibration, following the instructions.

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

A failed calibration will be indicated by the red cross icon, press the rotating arrow icon to attempt calibration again – if the problem persists see 'troubleshooting' or call the local supplier of Bedfont® products.

Return to the home screen by pressing the home icon.

Technical Specification

	piCO™	piCO baby™	Micro+™
Concentration range	0-150ppm	0-150ppm	0-500ppm
Display	Full colour touchscreen		
Detection principle	Electrochemical sensor		
Repeatability	≤±5%		
Accuracy	≤±2ppm/5%*		
Power	3 x AA (LR6 or equivalent) – up to 1000 minutes 1 x CR2032 Lithium coin cell		
T$_{90}$ response time	<30 seconds		
Operating temperature	15-40°C		
Storage/transport temperature	0-50°C		
Operating/storage/transport pressure	Atmospheric ±10%		
Operating humidity	15-90% RH (non-condensing)		
Storage/transport humidity	0-95% (non-condensing)		
Expected sensor operating life	5 years		
Sensor sensitivity	1ppm		
Sensor drift	<5% per annum		
Dimensions	Approx. 37 x 77 x 140 mm		
Weight	Approx. 215g (including batteries)		
Materials	Case: polycarbonate/ABS blend D-piece™: polypropylene SteriBreath™ Eco: paper OneBreath™: polypropylene		
H$_2$ cross interference	≤6%		

*whichever is greater

Safety Information and 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.
Consult electronic instructions for use	
The device includes a Radio Frequency (RF) transmitter (Bluetooth)	
CE mark	2797
EC-REP	EC | REP
Direct current	
Dispose of according to WEEE	
Serial number	SN
Unique device identification	UDI
Manufactured by	
Manufacture date	****
Indicator of Medical Device	MD

Environment

The piCO™, piCO^{baby™} and Micro^{+™} Smokerlyzer® products comply with the Medical Device Directive 93/42/EEC as amended by 2007/47/EC and the Medical Device Electromagnetic Compatibility standard EN 60601-1-2.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the piCO™, piCObaby™ and Micro^{+™} Smokerlyzer®, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. This equipment should be moved if necessary to avoid interference.

Guidance and manufacturer's declaration: Electromagnetic Immunity (IEC 60601-1-2)			
The Smokerlyzer® devices are intended for the use in the electromagnetic environment specified below. The customer or the user of the Smokerlyzer® should assure that it is used in such an environment.			
Emissions test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated Emissions EN55011:2007	30MHz to 1GHz	Met or exceeded	None
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated Immunity EN61000-4-3:2006 + A1:2008 + IS1 2009 + A2:2010	10V/m (1kHz 80%) 80MHz – 2.7GHz 385 MHz 27 V/m PM 18 Hz 450 MHz 28 V/m FM 1 kHz sine 710 MHz 9 V/m PM 217 Hz 745 MHz 9 V/m PM 217 Hz 780 MHz 9 V/m PM 217 Hz 810 MHz 28 V/m PM 18 Hz 870 MHz 28 V/m PM 18 Hz 930 MHz 28 V/m PM 18 Hz 1720MHz 28 V/m PM 217 Hz 1845 MHz 28 V/m PM 217 Hz 1970 MHz 28 V/m PM 217 Hz 2450 MHz 28 V/m PM 217 Hz 5240 MHz 9 V/m PM 217 Hz 5500 MHz 9 V/m PM 217 Hz 5785 MHz 9 V/m PM 217 Hz	Met or exceeded	Interference may occur in the vicinity of equipment marked with the following symbol:
Power Frequency Magnetic Immunity EN61000-4-8:2010	30 A/m magnetically sensitive equipment	Met or exceeded	None
ESD EN61000-4-2:1995+A1+A2	8kV contact 2, 4,8,15kV air	Met or exceeded	None

COdata+™ software – connecting to the PC
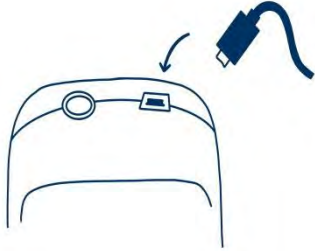
Place one end of the connection lead into the USB socket on the top of the Smokerlyzer® product.
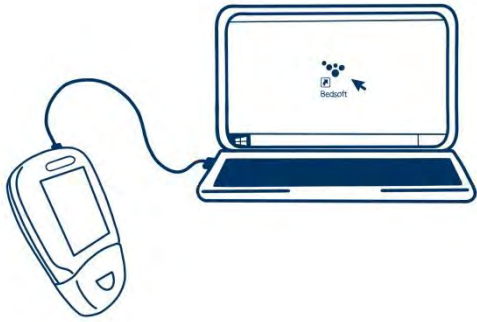
Connect the other end to the USB port on the PC.

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+™.

Buttons

Description	piCO™	piCO^{baby}™	Micro⁺™
Battery condition: full			
Battery condition: low			
Battery condition: empty			
Breath test			
Environmental test	N/A	N/A	
Settings			
Patient profiles	N/A	N/A	
View patient results	N/A	N/A	
Inhale			
Hold breath			
Countdown timer	15	15	15
Exhale			
ppm reading	**20** ppm CO	**20** ppm CO	**20** ppm CO
%COHb reading	**3.83** %COHb	**3.83** %COHb	**3.83** %COHb
Show %FCOHb reading	N/A		
%FCOHb reading	N/A	**3.83** %FCOHb	**3.83** %FCOHb
Ambient CO reading	N/A	N/A	**20** ppm CO
Home			
Change D-piece™			

Change traffic light cut-off levels			
Save	N/A	N/A	
Change breath-hold time	N/A	N/A	
History	N/A	N/A	
Mute			
Next step			
Low temperature			
High temperature			
Countdown to sensor change	15/03/2023	15/03/2023	15/03/2023
Change sensor			
Calibrate device			
Attach flow mete to gas canister			
Attach calibration adaptor to D-piece™			
Attached D-piece™ to device and turn on gas flow			
Unit calibrating			
Calibration successful			
Calibration failed			
Retry calibration			
Firmware version	Vers 2.0.1	Vers 2.0.1	Vers 2.0.1

N/A = Not Available on this device

Troubleshooting

The unit fails to turn on

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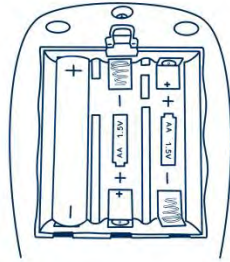
Ensure that the batteries are inserted the correct way around, matching the symbols moulded into the plastic.
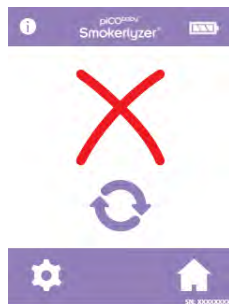
Zeroing has failed

If zeroing has failed, press the retry icon.

If zeroing continues to fail, contact Bedfont® or its local distributor for assistance.

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 Bedfont®, however Bedfont® recommends if the instrument may be reading incorrectly, try the test again with another device if available to get a comparison.

Alternatively, complete a functional check using Bedfont® check gas or send back to Bedfont® or its local distributor. The check gas required is Bedfont® 20ppm carbon monoxide in air.

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, open the fine control valve or regulator.

5. Allow the gas to flow at 1 litre per minute.

6. Allow the gas to flow through the instrument for the duration of the test, again monitoring the rate of flow.
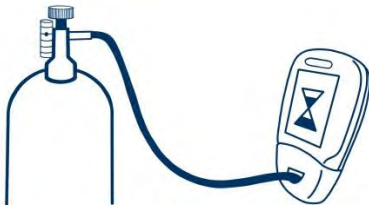
7. If the final displayed value is less than 15ppm or higher than 25ppm, stop the test and perform a calibration or send back to Bedfont® for a free of charge calibration, following the instructions.

Warranty

Bedfont® Scientific Limited warrants the piCO™, piCO^{baby}™ and Micro⁺™ Smokerlyzer® products (excluding batteries) to be free of defects in materials and workmanship for a period of five 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 and prepaid, to Bedfont® or the local representative.

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 Bedfont® or its distributor for disposal instructions.

Returns

Please contact Bedfont® or its local distributor for instructions on returning goods.

Responsible Manufacturer and Contacts

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Harrietsham,
Maidstone, Kent,
ME17 1JA
United Kingdom

www.bedfont.com
ask@bedfont.com
0044 1622 851122

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

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

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