

Smokerlyzer[®] Range

For use with Micro[™] Smokerlyzer[®]

User manual



CE
2797

Our family, innovating health, for yours.



Definitions

WARNING: Indicates a potentially hazardous situation, which, if not avoided, may result in 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 device 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.

WARNING: Avoid exposure to known sources of EMI (electromagnetic interference) such as Magnetic Resonance Imaging (MRI) systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors.

WARNING:  Keep the Smokerlyzer® outside the MRI scanner room.

CAUTION: Ensure the device is used within the stated operating temperature and humidity ranges. Operating temperature is 15 - 40°C (59°F - 104°F). 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

Definitions.....	1
Important Information/Reminders.....	1
Introduction	4
Compliance	4
Intended Use.....	4
Contraindications.....	4
Instrument Layout.....	5
User Interface	6
Taking a breath test	7
Conducting an ambient test.....	11
Patient Profiles.....	12
Reviewing history.....	15
Changing date and time.....	16
Changing breath holding time	17
Changing breath testing thresholds.....	18
Maintenance Reminders.....	19
Maintenance	21
Calibration.....	22
Technical Specification.....	27
Safety Information and Device Symbols.....	28
Environment	29
COdata ⁺ ™ software – connecting to the PC.....	30
Buttons.....	31
Troubleshooting.....	33
Warranty	36
Returns.....	36
Responsible Manufacturer and Contacts.....	36

Introduction

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

The Micro⁺™ Smokerlyzer® displays CO ppm, %COHb and %FCOHb. 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⁺™ Smokerlyzer® device is CE marked according to the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

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

Intended Use

The Micro⁺™ Smokerlyzer® product is a breath carbon monoxide device intended for multi-patient use by healthcare professionals in smoking cessation programmes and research. It 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



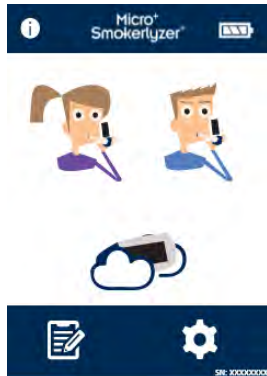
Home Screen

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



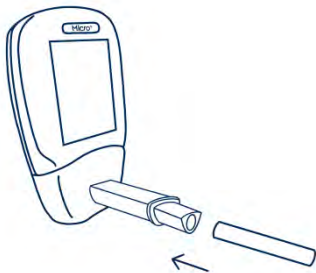
The information screen displays information about the device and sensor.

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.

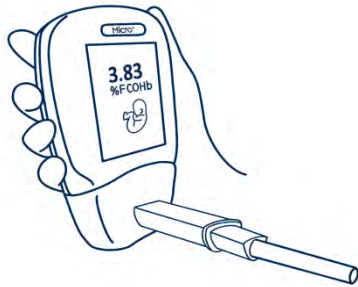
Press the home button at any time to cancel the breath test.



A beep will sound during the last three seconds of the countdown.



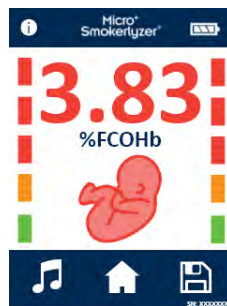
Blow slowly into mouthpiece, aiming to empty lungs completely.



The ppm and equivalent %COHb and/or %FCOHb levels will rise and hold onscreen.



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.

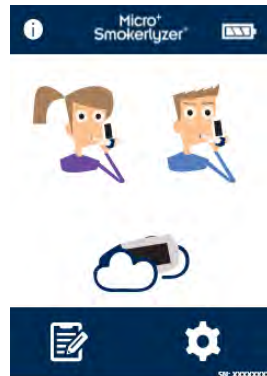
To repeat breath test, press the home icon once to return to the home screen and repeat steps.

To save the reading, 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



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.



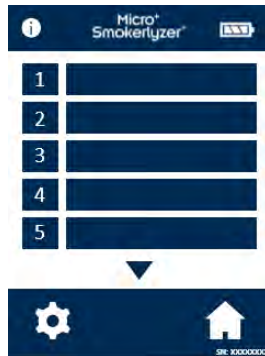
The device may show this screen when the sensor is zeroing.



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



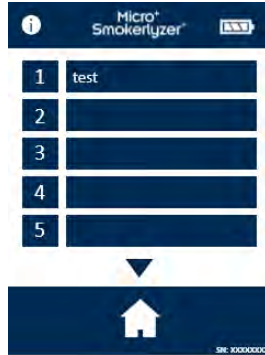
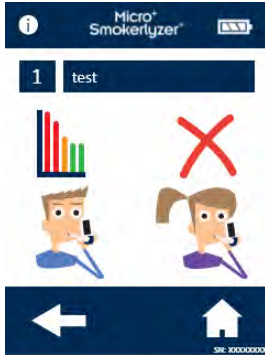
All patient profiles saved on the device will be listed here. To view patient information, press the relevant patient profile block.



To change the name of the patient, press the text box icon.



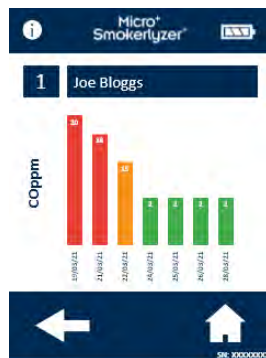
Press the letters required. Click the save icon to confirm or the back arrow to return.



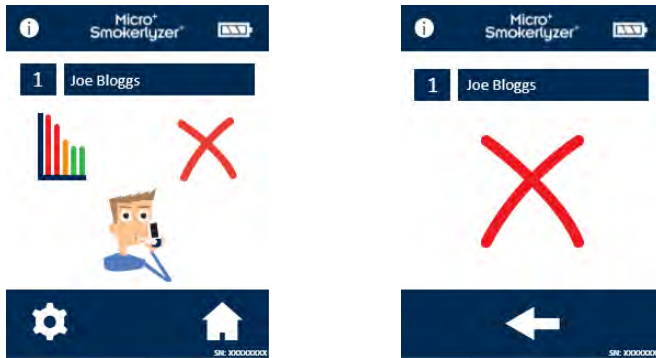
Once the patient profile name has been updated, the name will show when viewing the patient profile screen.



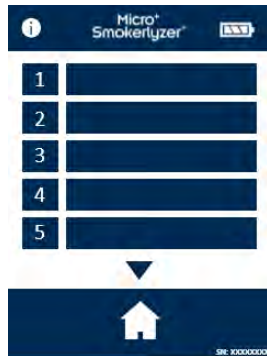
If 'start breath test' is selected from this screen, the breath test will be automatically saved to the profile. Once the type of breath test has been assigned to the patient, only one symbol will appear.



To access the patient's breath test results history, press the graph icon. This will then bring up the patient's testing history.

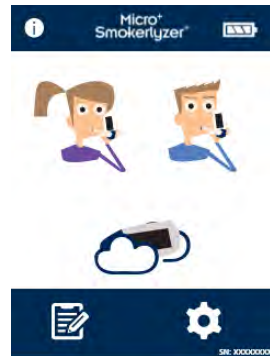


To delete a patient profile, press the delete icon. To confirm, press the delete icon again.



Once confirmed, the patient profile will no longer appear on the patient profile list.

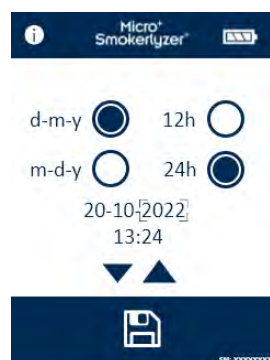
Changing date and time



Press the settings icon.



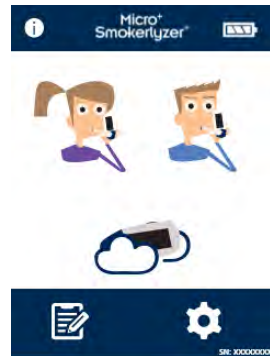
Press the date/time icon.



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

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

Changing breath holding time



Press the settings icon.



Press the breath holding time icon.

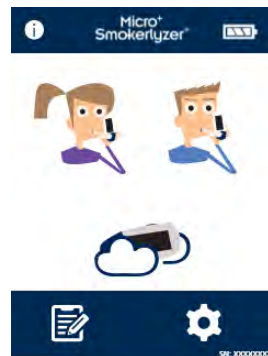


Use the arrows to adjust the breath holding time. Press the save icon to save changes.

Changing breath testing thresholds

Traffic light colour	Description	Reading (ppm)
Green	Non-smoker	0 - 6
Amber	Borderline	7 - 9
1 Red	Smoker – low addicted	10 - 15
2 Red	Smoker – moderately addicted	16 - 25
3 Red	Smoker – heavily addicted	26 - 35
3 Red Flashing	Smoker – very heavy addicted	36 +

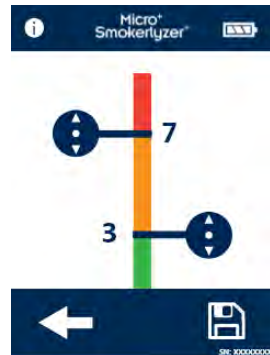
This table shows the pre-set breath testing thresholds.



Press the settings icon.



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



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. This reminder cannot be bypassed.



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. The Micro⁺™ Smokerlyzer® requires calibrating every 6 months.
6. 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.
7. Replace batteries when indicated by the empty symbol.
8. Bedfont® recommend removal of the batteries when the device is not used for prolonged periods of time to prevent leakage.
9. Replace breath sampling D-piece™ every 30 days or if visibly soiled or contaminated. The Micro⁺™ Smokerlyzer® will give a reminder during start-up when the D-piece™ should be replaced, see 'change D-piece™' symbol.
10. 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.

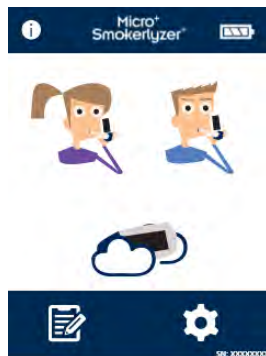
Cleaning

1. The Smokerlyzer® products are moulded with anti-microbial additive technology for optimum infection control and bacterial efficacy. Bedfont® recommends wiping the device 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 device be immersed in liquid or splashed with liquid

Calibration

The Smokerlyzer® devices must be calibrated within 17 - 25°C (64 - 77°F). If it is too cold to calibrate (< 17°C / 64°F) 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 / 77°F) 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 once to enable.



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.



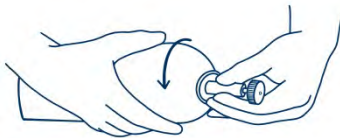
Once this has been successfully carried out the device will perform a zero; do not apply gas at this stage.



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.



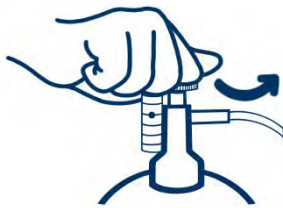
Attach a D-piece™ to the calibration adaptor. Press the arrow to continue the calibration process.



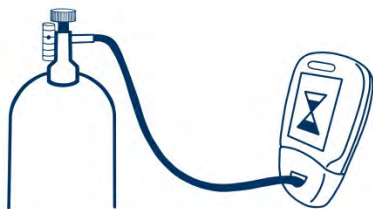
Insert a D-piece™ into the device and turn on the gas. Press the arrow to continue.



Allow the gas to flow at 1 litre per minute.



Allow the gas to flow through the device for the duration of the test, again monitoring the rate of flow.



If the final displayed value is less than 18 ppm or higher than 22 ppm, 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

Concentration range	0 – 500 ppm
Display	Full colour touchscreen
Detection principle	Electrochemical sensor
Repeatability	≤ ± 5%
Accuracy	≤ ± 2 ppm/5%*
Power	3 x AA (LR6 or equivalent) – up to 1000 minutes 1 x CR2032 Lithium coin cell
T₉₀ response time	< 30 seconds
Operating temperature	15-40°C (59°F-104°F)
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)
Sensor operating life	5 years
Sensor sensitivity	1 ppm
Sensor drift	< 5% per annum
Dimensions	Approx. 37 mm X 77 mm X 140 mm
Weight	Approx. 215 g (including batteries)
Materials	Case: polycarbonate/ABS blend Anti-microbial additive D-piece™: polypropylene SteriBreath™ Eco: paper OneBreath™: polypropylene
H₂ cross interference	≤ 6%

*whichever is greater


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 electronic instructions for use	
Direct current	
CE mark	
Type BF applied part	
Dispose of according to WEEE	
Serial Number	
Unique device identifier	
Indicator of Medical Devices	
Magnetic Resonance (MR) unsafe	
Manufactured by and date	
Bedfont® Logo	

Environment

The Micro⁺™ Smokerlyzer[®] product complies 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.

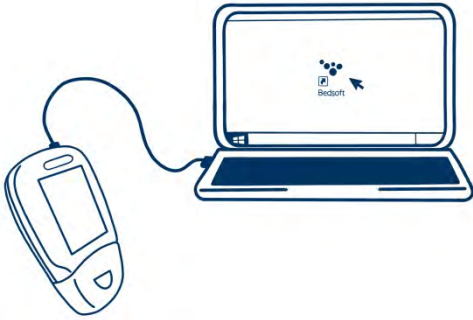
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Micro⁺™ Smokerlyzer[®], including cables specified by the manufacturer. Otherwise, degradation of the performance of this 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%) 80 MHz – 2.7 GHz 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 1720 MHz 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	8 kV contact 2, 4, 8 ,15 kV air	Met or exceeded	None

COdata⁺™ software – connecting to the PC














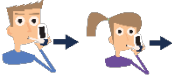





Place one end of the connection lead into the USB socket on the top of the Smokerlyzer[®] product.





















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

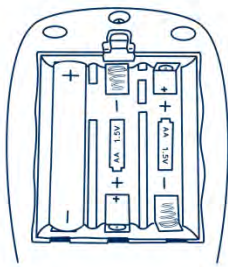
Description	Micro ⁺ ™
Battery condition: full	
Battery condition: low	
Battery condition: empty	
Breath test	
Environmental test	
Settings	
Patient profiles	
View patient results	
Inhale	
Hold breath	
Countdown timer	
Exhale	
ppm reading	20 ppm CO
%COHb reading	3.83 %COHb
Show %FCOHb reading	
%FCOHb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

Change traffic light cut-off levels	
Save	
Change breath-hold time	
History	
Mute	
Next step	
Low temperature	
High temperature	
Countdown to sensor change	 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

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

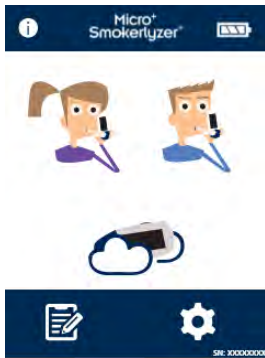
Smokerlyzer® products are calibrated before leaving Bedfont®, however Bedfont® recommends if the device may be reading incorrectly, try the test again with another device if available to get a comparison. Alternatively, check the function using Bedfont® check gas or send back to Bedfont®. The check gas required is Bedfont® 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.



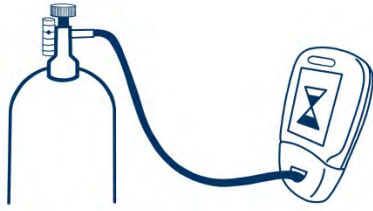
4. When prompted by the 'exhale' symbol, open the fine control valve or regulator.



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



6. Allow the gas to flow through the device for the duration of the test, again monitoring the rate of flow.



7. If the final displayed value is less than 18 ppm or higher than 22 ppm, 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 Micro⁺™ Smokerlyzer® product (excluding batteries) to be free of defects in materials and workmanship for a period of 5 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

Bedfont® Scientific Ltd.
Station Yard, Station Road,
Harrietsham,
Maidstone, Kent,
ME17 1JA
United Kingdom

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



bedfont[®]
est. 1976

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

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

Our family, innovating health, for yours.

Visit www.bedfont.com/resources to view this document in other languages.



Bedfont[®] Scientific Ltd.
Station Road, Harrietsham, Maidstone,
Kent, ME17 1JA England
Tel: +44 (0)1622 851122 Fax: +44 (0)1622 854860
Email: ask@bedfont.com Web: www.bedfont.com



Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands.

© Bedfont[®] Scientific Limited 2024

Issue 15 - September 2024, Part No: LAB679_USA
Bedfont[®] Scientific Limited reserves the right to change or update this literature without prior notice.
Registered in: England and Wales. Registered No: 1289798

Rxonly



MD 502905