



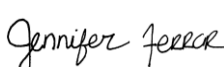
**SOP - 9**  
**USE AND CALIBRATION OF piCO+ and piCO<sup>simple</sup> SMOKERLYZERS**

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### USE AND CALIBRATION OF piCO+ and piCO<sup>simple</sup> SMOKERLYZERS

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Definitions/Abbreviations	
CO	Carbon Monoxide
CRF	Case Report Form
PI	Principle Investigator
PPM	Parts Per Million
SOP	Standard Operating Procedure

#### 1. PURPOSE:

- To provide step-by-step instruction for use of piCO+ and piCO<sup>simple</sup> smokerlyzers in research.

#### 2. REFERENCES:

- piCO+ Smokerlyzer device user manual:  
Hard copy of manual is in the Research Store in 5D11. piCO<sup>simple</sup> device user manual.

#### 3. PERSONNEL REQUIRED AND LEVEL OF EXPERTISE:

- Investigator and research team
- Training required

#### 4. MATERIALS AND EQUIPMENT REQUIRED:

- AA Batteries
- Alcohol free hand foam sanitiser
- Breath sampling D-Pieces
- Calibration kit:
  - 20ppm calibration gas
  - 50ppm bump test gas
  - Fine control valve, flow indicator, calibration adaptor and tube
- Carry pouch
- Disposable mouthpieces
- Examination gloves
- Monitor cleaning wipes (alcohol free)
- Paperclip
- piCO+ / piCO<sup>simple</sup> Smokerlyzer
- Storage pouch
- User manual

#### 5. PROCEDURE:

##### 5.1 When:

When levels of recent smoking need to be ascertained through the use of a breath CO monitor such as piCO+ and piCO<sup>simple</sup> Smokerlyzers.

##### 5.2 Calibrating piCO+ and piCO<sup>simple</sup> Smokerlyzers:

**\*\*PLEASE NOTE THAT SUBTLE DIFFERENCES EXIST BETWEEN DEVICES.**

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### ALWAYS REFER TO THE CORRECT MANUAL FOR YOUR MODEL\*\*

The piCO+ Smokerlyzser should be calibrated in house at least every 6 months and at the start of every new research study. The piCO<sup>simple</sup> instead requires a yearly functional check. If you suspect that either model is reading inaccurately you can perform a bump test to check function and re-calibrate if required.

Please note that an unexpected reading of CO presence in a non-smoker may be indicative of an ambient level of CO in surrounding air or the effects of passive smoking. False readings may also be generated if alcohol is present on a participant's breath or from hydrogen generated by their digestive system. Inaccuracies can also be caused if a device is too cold or if the battery is leaking.

All unexpected readings should be checked with your project supervisor/P.I. and, where necessary, devices should be tested and re-calibrated.

The calibration kit is available from TARG's Research Store in 5D11.

Please allow plenty of time for calibrating your device ahead of testing. In the event of calibration problems the device will need to be sent to the manufacturer (Bedfont) for servicing which can take several weeks to complete.

#### **5.2.1 20ppm CO in air calibration:**

Step by step calibration instructions are provided in the manual for each model and should be consulted for each calibration. In addition please also observe the guidance listed below:

- The piCO+ Smokerlyzser is calibrated using 20ppm CO in air calibration gas.
- It is important for the gas to flow through the device at 1 litre per minute – you must control the flow of gas so that the ball bearing in the flow indicator stays at the middle line. Please note that this can be tricky to achieve. If you have difficulties Bedfont recommend getting the gas to flow through at the right speed whilst it is disconnected from the breath sampling D-piece and then attach when flowing consistently.
- If a device fails to calibrate correctly then the process must be repeated. You should wait 30 minutes between calibrations, allowing the device to settle and fresh air to circulate through the sensor by removing the D-Piece.
- Once calibration is complete turn off the 20ppm gas flow and ensure that you unscrew the fine control valve and flow indicator from the gas canister and replace the dust cap. If valve is left in the can, the gas could escape.
- After use return the 20ppm calibration gas to TARG's Research Store in 5D11 and advise your project supervisor of the date of the successful calibration.

CoVita have a helpful interactive video explaining how to perform a device calibration. This is available on youtube: <https://www.youtube.com/watch?v=IGRnhpX7kzo>

#### **5.2.2 50ppm bump testing:**

After a successful calibration the piCO+ Smokerlyzser should be 'bump' tested using 50ppm CO in air calibration gas.

- Wait 30 minutes after calibration before performing the bump test, allowing the device to settle and fresh air to circulate through the sensor by removing the D-Piece.
- Select a patient test as normal but at point of exhalation (third beep) flow 50ppm CO in air gas into the device as when calibrating until test completes (back symbol is displayed at bottom of screen).

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- Tolerance of +/- 10% is permitted (for 50ppm calibration gas this is +/- 5ppm). Please take note of the certified values of the 50ppm and 20ppm gas when calculating expected readings. If unsure contact Bedfont for advice.
- After use return the 50ppm calibration gas to TARG's Research Store in 5D11.
- Log the date of successful calibration and the value of your obtained bump test readings with your project supervisor for central records.

#### 5.2.3 Unit re-set:

Zero-ing tests must be completed in a room full of fresh air, with no residual calibration gas. This is to prevent a creep in bump test readings. If this happens, or there are other difficulties calibrating the unit, then a unit reset should be undertaken.

*To reset the unit:*

- Remove the battery cover on the underside of the unit.
- Unwind a paperclip and use one end to press the reset button located in the battery bay (see device manual for exact location).
- The unit will beep.
- Remove and replace one battery.
- Turn on the device. The lights will flash in a traffic light sequence and the device will beep.
- When prompted perform a zero-ing test, 20ppm calibration and 50ppm bump test as outlined above.

If problems persist and all the above steps have been completed the device may need to be sent for repair or replaced. Please refer to the Research Group Administrator for advice.

#### 5.3 How:

**\*\*PLEASE NOTE THAT SUBTLE DIFFERENCES EXIST BETWEEN DEVICES.  
ALWAYS REFER TO THE CORRECT MANUAL FOR YOUR MODEL\*\***

Step by step operating instructions are detailed in the instruction manual for your device. In addition the following steps and instructions must be observed:

- Gloves must be used when handling the monitor, including when fitting mouthpieces.
- Prepare the device by inserting the breath sampling D-piece. These should be changed at least every 30 days and immediately if visually soiled or contaminated.
- Attach a disposable mouthpiece to the breath sampling D-piece. A new cardboard or plastic disposable mouth piece should be used for each person being tested. Cardboard pieces are slotted around the D-Piece whereas the plastic mouthpieces slot inside the circular hole in the D-Piece.
- Before you begin the test explain to your participant that you are carrying out a carbon monoxide breath test, which provides information about recent smoking. Explain that they will need to take a deep breath, hold this in for 15 seconds and then exhale steadily into the tube to empty their lungs completely while ensuring they keep the area at the back of the device clear for air to flow through.
- When the participant is ready start the 15 second count down and instruct them to inhale a deep breath. Pass the device to the participant and show them the countdown on screen. Inform them that when the countdown reaches zero they should exhale steadily into the tube until they have exhaled all the air from their lungs.
- Ensure breath is held throughout the countdown.

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- An audio beep sounds the last three seconds of the countdown at which point instruct them to exhale slowly into the mouthpiece when the countdown reaches zero. They should aim to empty their lungs as much as possible.
- If the participant is a smoker the ppm reading will rise, lights will illuminate and the device will beep at an increasing frequency. Reassure the participant that this is normal, and just tells us that they have smoked recently. The highest level detected is displayed on the reader. This is the figure you should record in your CRF. Refer to your study protocol for cut off values for study inclusion/exclusion criteria. You can silence the device using a single click.
- Remove the breath sampling D-piece to allow the device to air out between breath samples.
- If the device will not be used for a period of time remove the batteries. Replacement batteries, if required, are available from TARG's Research Store in 5D11.
- Batteries should be regularly inspected.

#### **5.4 Cleaning, storage and infection control:**

It is important to maintain hygienic practices when using the piCO+ and piCO<sup>simple</sup> monitors. Monitors must be kept clean and stored appropriately.

Vapours from alcohol based cleaning agents can damage the device sensor. Use only alcohol free wipes to clean the monitor and alcohol free hand sanitiser on your own hands. Take care to make sure the device is not immersed or splashed with liquid.

When not in use and between participants the breath sampling D-piece should be removed allowing the device to air out. When transporting the device or for storage between test sessions use the carry bag and storage pouch to keep the device safe and free from dust and contaminants. Devices should not be left in the cold overnight as this may affect the accuracy of readings. If the device will not be used for a period of time remove the batteries.

The breath sampling D-piece must be replaced every 30 days or if contaminated or visibly soiled. A log of the dates D-pieces are changed should be kept in the study master file. Please note that D-pieces cannot be cleaned or sterilised. A new disposable mouthpiece should be used for each new participant.

Always use gloves throughout the procedure, including when fitting mouthpieces. Hands should be washed regularly and alcohol free hand sanitiser used.

#### **6. TROUBLE SHOOTING:**

<b>Problem</b>	<b>Solution</b>
Technical issues:	<p><b>Please check the device manual troubleshooting sections:</b></p> <p><b>piCO+ Smokerlyzer:</b> Research Store in 5D11</p> <p><b>piCO<sup>simple</sup> device manual:</b> Research Store in 5D11</p> <p><b>Supplier: Bedfont</b></p> <p><b>Website:</b> <a href="http://www.bedfont.com/uk/english/support">http://www.bedfont.com/uk/english/support</a> <b>Email:</b> <a href="mailto:ask@bedfont.com">ask@bedfont.com</a> <b>Tel:</b> 01622 851122</p> <p><b>Distributor and out of warranty support: Intermedical</b></p>

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	<b>Website:</b> <a href="http://www.intermedicalsupport.co.uk/">http://www.intermedicalsupport.co.uk/</a>
Any other problems:	<b>TARG Laboratory phone:</b> 07957 334 265  <b>Professor Marcus Munafò</b> (0117) 954 6841 internal 46841 <a href="mailto:Marcus.Munafò@bristol.ac.uk">Marcus.Munafò@bristol.ac.uk</a>  <b>Dr Angela Attwood</b> (0117) 331 7450 internal 17450 <a href="mailto:Angela.Attwood@bristol.ac.uk">Angela.Attwood@bristol.ac.uk</a>