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Issue 1

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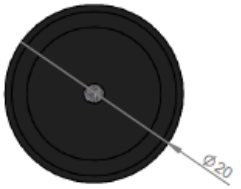
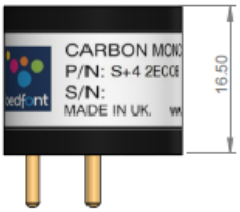
New piCO™, piCO$^{baby™}$ & Micro$^{+™}$ Smokerlyzer®
No Calibration Rationale

Bedfont Scientific Ltd recommends that calibration is not required for the piCO, piCObaby and Micro+ Smokerlyzer products for a period of 5 years. Traditionally it was recommended that the devices were calibrated using disposable cylinders of calibration gas. However it was noted that many users globally were not following this guideline and Bedfont were in fact receiving a high percentage of units returned as faulty due to miss-calibration. An investigation was launched into this and the results showed that in the period of April 2010 – June 2012 an overwhelming 51% of all piCO+ repairs were attributed to miss-calibration of the devices. Annex a



Some reasons for this included:

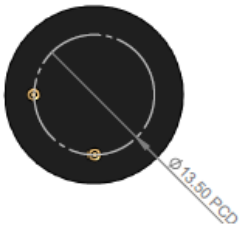
- Non-Bedfont uncertified/inconsistent quality calibration gas
- Calibration gas running out during a calibration
- Zeroing the monitor whilst applying gas as opposed to fresh air
- The incorrect flow rate being used to calibrate



Having discovered the high percentage of devices that were ironically being made less accurate by failing the calibration, Bedfont embarked upon investigating the level of risk involved in not calibrating them.

Accuracy

The Sensors used in Bedfont Smokerlyzer devices have been rigorously tested and provide excellent accuracy at measuring the target gas, Carbon Monoxide (CO) to a level of less than 1ppm.



Cross-sensitivity

The sensors have been specifically developed for accurate breath analysis and therefore have less than 6% cross-sensitivity to Hydrogen (H_2). H_2 is a highly abundant gas in the human body due to malabsorption of sugars in food, CO sensors confuse H_2 for CO and therefore false higher readings can be produced. Therefore as the Bedfont devices have less than 6% cross-sensitivity to H_2, even a level of 50ppm H_2 (which is very high) would increase the reading shown by less than 3ppm in the worst case. Some CO sensors can have much higher cross-sensitivity to H_2 (10-40%) and this increases the risk of obtaining false positive readings as a result of high H_2 levels on the patient's breath.

Stability

As the devices are required for daily use in a number of settings it is sometimes very difficult to keep track of their maintenance. Therefore Bedfont has been working tirelessly to create the most stable product that does not require regular maintenance. This has resulted in a sensor that has less than 5% drift per annum. This is the main factor that dictates whether calibration is required and to put this into perspective in terms of risk:

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Risk of a false positive reading:

General globally accepted ppm value for smoker	>10ppm[1, 2, 3, 4 & 5]
Worst case non-smoker reading	3ppm
Potential maximum sensor drift over 5 years	25%
Worst case positive drift on worst case reading for non-smoker (5th year)	3ppm x 25% = 0.75 (**1ppm on device)**
Potential maximum H_2 cross-sensitivity	6%
Worst case H_2 reading	50ppm (H_2) x 6% = **3ppm (CO)**
Total worst case reading for a non-smoker	**7ppm**

Risk of a false negative reading:

General globally accepted ppm value for smoker	>10ppm[1, 2, 3, 4 & 5]
Worst case smoker reading	11ppm
Potential maximum sensor drift over 5 years	25%
Worst case negative drift on worst case reading for smoker (5th year)	11ppm x 25% = 2.75 (**-3ppm on device)**
Potential maximum H_2 cross-sensitivity	6%
Worst case H_2 reading	50ppm (H_2) x 6% = **3ppm (CO)**
Total worst case reading for a smoker	**11ppm**

As you can see from both sets of results there is no risk of either false-positive readings or false-negative readings in the worst cases of drift combined H_2 cross-sensitivity by not calibrating the devices for a period of 5 years. In reality this risk would be even lower due to the average performance of the sensor with regard to drift and H_2 cross-sensitivity being better than the stated worst case performance figures.

Conclusion

In conclusion Bedfont recommend not calibrating these devices as they will remain very accurate for the expected life of the device (5 years). Bedfont are so confident of this that a 5 year warranty is given with all Smokerlyzer products. Therefore the unit will not prompt for calibration, however should the user want to check the calibration or be instructed to calibrate the unit they can still do this by following the instructions in the product's manual.

The information in this document is accurate as of the date of publication and illustrates Bedfont Scientific Ltd's long serving commitment to product quality, ease of use and cost effectiveness.

Bibliography:

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4. Sandberg A. 2011: Assessing Recent Smoking Status by Measuring Exhaled Carbon Monoxide Levels http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0028864
5. Chatkin G. et al, 2010: Evaluation of the exhaled carbon monoxide levels in smokers with COPD http://www.scielo.br/scielo.php?pid=S1806-37132010000300011&script=sci_arttext&tlng=en

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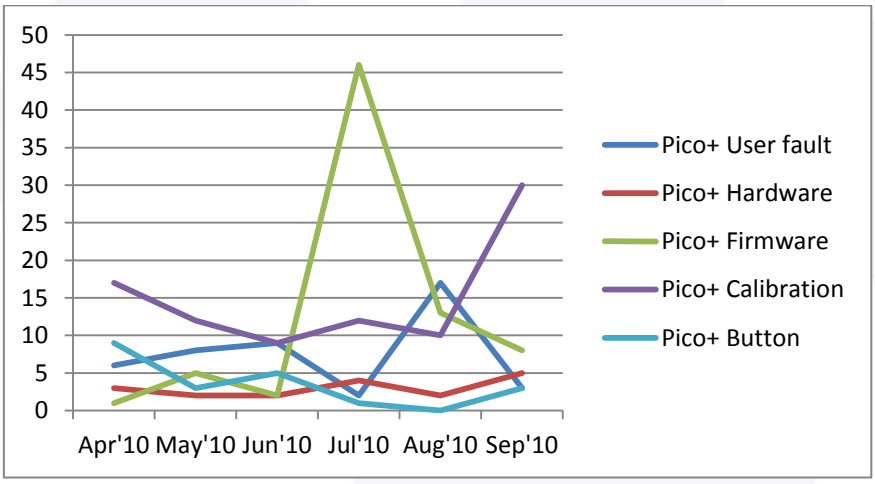
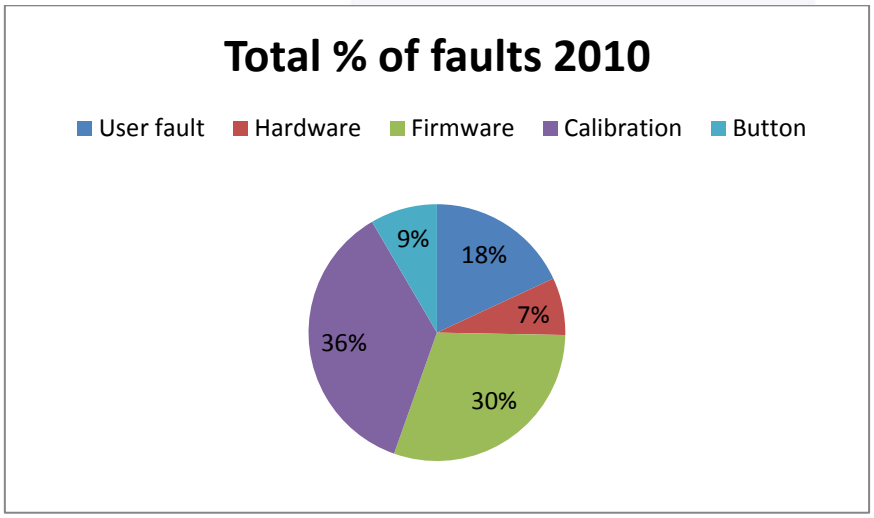
Annex A

2010

	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Apr'10	**6**	**3**	**1**	**17**	**9**
May'10	**8**	**2**	**5**	**12**	**3**
Jun'10	**9**	**2**	**2**	**9**	**5**
Jul'10	**2**	**4**	**46**	**12**	**1**
Aug'10	**17**	**2**	**13**	**10**	**0**
Sep'10	**3**	**5**	**8**	**30**	**3**

	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Total	45	18	75	90	21





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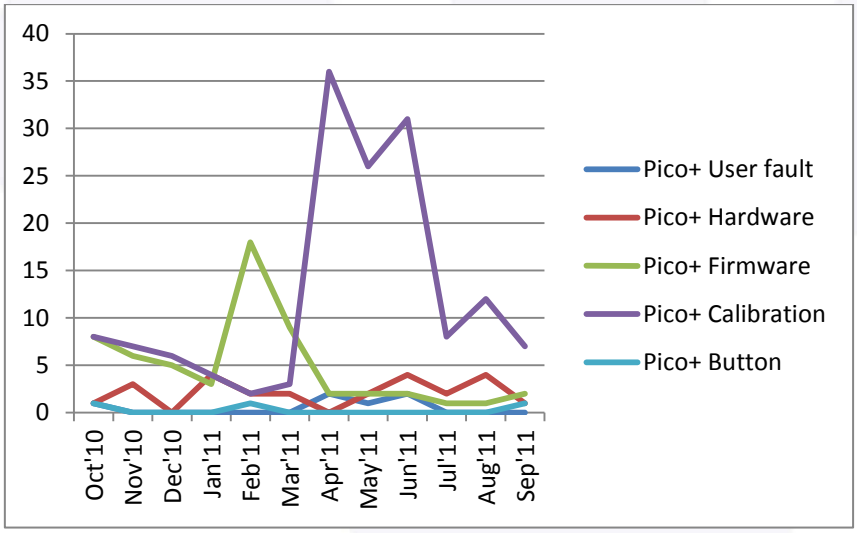
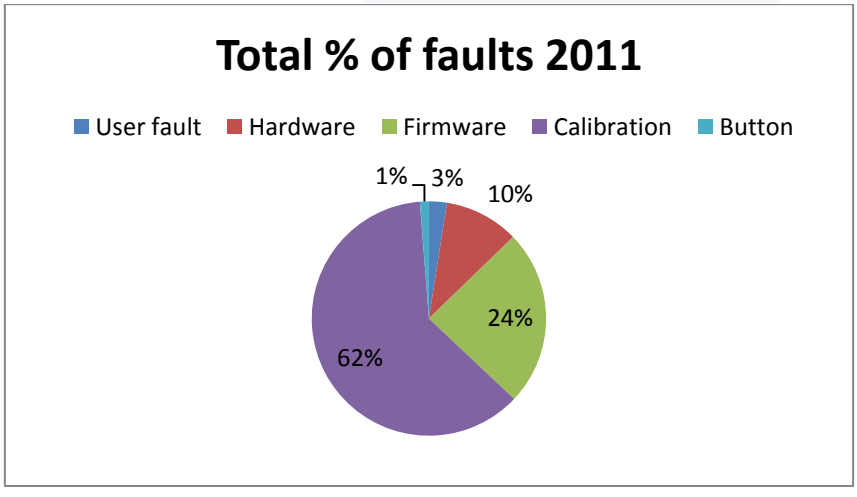
2011

	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Oct'10	1	1	8	8	1
Nov'10	0	3	6	7	0
Dec'10	0	0	5	6	0
Jan'11	0	4	3	4	0
Feb'11	0	2	18	2	1
Mar'11	0	2	9	3	0
Apr'11	2	0	2	36	0
May'11	1	2	2	26	0
Jun'11	2	4	2	31	0
Jul'11	0	2	1	8	0
Aug'11	0	4	1	12	0
Sep'11	0	1	2	7	1

	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Total	6	25	59	150	3





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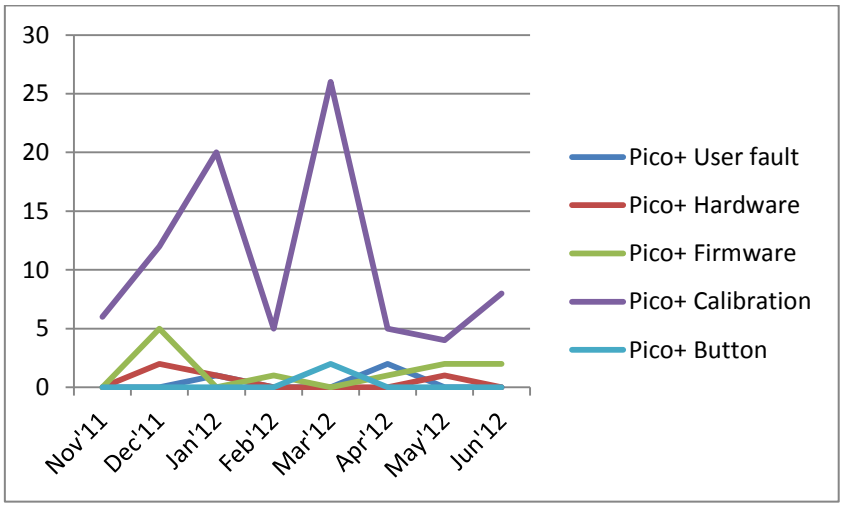
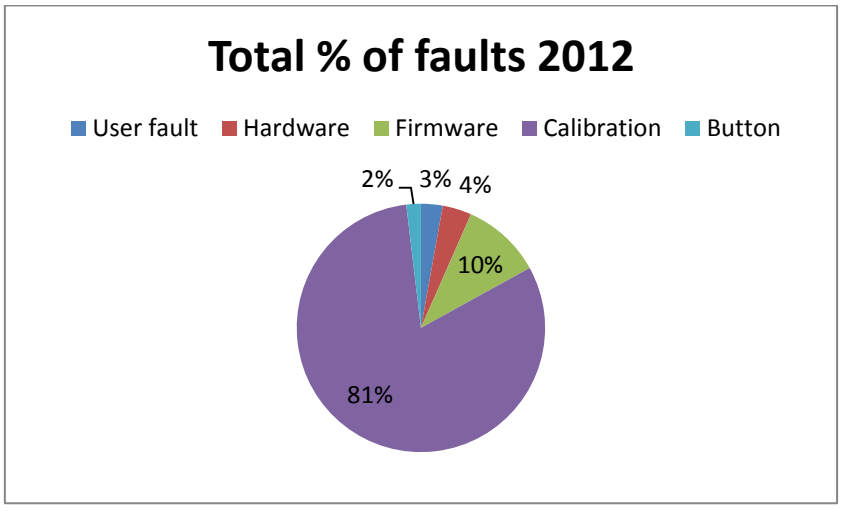
2012

	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Nov'11	**0**	**0**	**0**	**6**	**0**
Dec'11	**0**	**2**	**5**	**12**	**0**
Jan'12	**1**	**1**	**0**	**20**	**0**
Feb'12	**0**	**0**	**1**	**5**	**0**
Mar'12	**0**	**0**	**0**	**26**	**2**
Apr'12	**2**	**0**	**1**	**5**	**0**
May'12	**0**	**1**	**2**	**4**	**0**
Jun'12	**0**	**0**	**2**	**8**	**0**

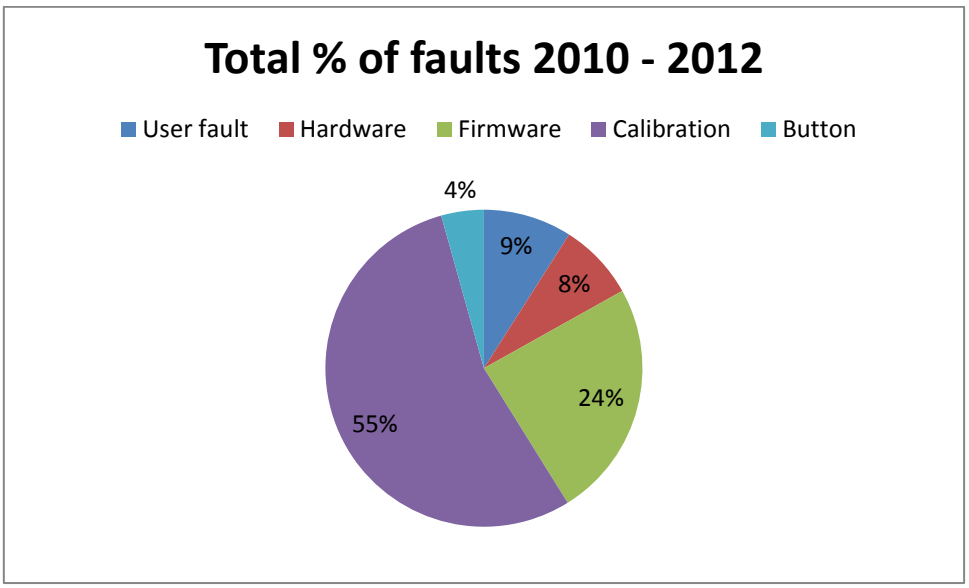
	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Total	3	4	11	86	2





Total faults from April 2010 - June 2012

	Pico+				
	User fault	Hardware	Firmware	Calibration	Button
Total	54	47	145	326	26



Key

Firmware - fault found with firmware on device
Hardware - fault found with hardware on device
Calibration - unit miss-calibrated by user
User Fault - fault found relating to customer misuse other than miss-calibration