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Objective

Logan Research Ltd was asked to evaluate 3 Senko BMC-2000 CO monitors and make some comparisons with a Bedfont piCO⁺ monitor. This evaluation was prompted by adverse feedback in regard to the Senko units in the UK marketplace (see annex 1) and Bedfonts own data.

Introduction

In November 2008 an examination was undertaken on the three Senko BMC-2000 monitors to test its functional performance and compare its performance with the Bedfont piCO⁺. From the three Senko units tested only one worked as intended, the other two partially functioned on one day and not at all on some other days.

It was clear that the Senko unit was in many ways a very close engineering copy of the Bedfont piCO⁺, particularly in regard to the gas sampling path and its moulding.

Another observation made was that the Senko unit used an industrial grade CO sensor Type SS1128 which is unsuitable for use in a low gas concentration level medical CO analyser due to its poor signal to noise ratio and high cross sensitivity to Hydrogen which is ever present in human test subjects.

The UK agent for the Senko BMC-2000 is UBLOW Ltd Units supplied by UBLOW Ltd in the UK appear not to be serial numbered by UBLOW LTD.

Gas Testing:

The working Senko unit was tested as per the standard test procedure using 3 levels of Carbon Monoxide and a flow rate of 0.5Lpm. See Table below.

20ppm Applied	50ppm Applied	250ppm Applied
20	54	90
19	53	90
20	53	90
20	53	90
19	53	90

The unit was found to respond very quickly implying little averaging of readings when gas was applied. Also the specification clearly states the monitor's range is 0-100 ppm and when the monitor reaches 99 ppm it instantly drops to 90 ppm implying lack of dynamic range, saturation of the analog electronics or just an incorrect maximum set limit value in firmware. This would not be the case in a well designed unit.

Breath Testing:

Breath sample	piCO⁺	BMC-2000
Smoker 1		
Test 1	20	19
Test 2	20	18
Test 3	20	18
Test 4	20	18
Test 5	20	19
Smoker 2		
Test 1	16	14
Test 2	16	13
Test 3	16	13
Test 4	16	13
Test 5	16	13
Smoker 3		
Test 1	40	34
Test 2	39	33
Test 3	40	33
Test 4	41	34
Test 5	39	33
Non Smoker		
Test 1	4	5
Test 2	4	6
Test 3	4	6
Test 4	4	6
Test 5	4	6

From the results gathered above using 4 subjects the readings from the BMC-2000 were very inconsistent compared to the piCO⁺ readings. The manual for the BMC states in its specification that the accuracy is "+/-3% of full scale or 1ppm" and from the results above a lot of the readings are up to 3 ppm out compared with the piCO⁺.
From the above data one can deduce that the Senko unit suffered from a poor zeroing and poor calibration and/or poor temperature compensation firmware design and time window settings.

Hydrogen Cross sensitivity:

One of the intermittently working Senko units was tested with 100 ppm hydrogen to check the sensors cross sensitivity.
The monitor gave the following readings:
23, 22, 23, 21, 22 ppm

The specification states a hydrogen cross sensitivity of 15%(<=10% is the desireable maximum limit for medical use), the test made shows an average of approximately 22%. This could cause high inaccuracy with many patients that give off high hydrogen levels (most patients) and therfore false positive results ie, non-smokers could be classified as smokers.

Results from a gas test performed on one of the UBLOW BMC monitors in the market (the UBLOW monitors are not serial numbered in any way). The test was done using four different gas values as shown below (one being air). The monitor was first zeroed in a clean air environment then calibrated following the procedure in the UBLOW

manual. Each test was performed 3 times and the monitor was given a minute between tests to zero. The results are shown below:

Test Gas	Reading (ppm)		
20 ppm CO	20	17	19
50 ppm CO	45	38	43
100 ppm H2	38	35	35
Air	3	1	1

From the results it can be seen the monitor does not retain its accuracy at a constant rate and when bump tested with different values the readings were very in-accurate.
It was also noticed during testing that the monitor displayed very unstable results. The reading would jump 2 ppm at a time and sometimes would only jump 3-5 ppm. Compared to the piCO⁺'s live reading display showing each ppm increment the UBLOW monitor is unstable and in-accurate even at low gas values.
It should also be noted that the monitor has a very large cross sensitivity to Hydrogen which can be found in most patients, especially those with lactose intolerance or similar illnesses. The piCO⁺ only has a cross interference to hydrogen of <10%. High hydrogen levels could cause abnormal high readings or in a recently quit smoker to get very high readings on the UBLOW monitor which could effect their confidence in quitting.

Temperature testing

This shows the performance testing carried out on the Senko monitors at different temperature ranges. The test was going to be performed on three of the monitors that we acquired from a UK customer. These units have been in the UK for approximately no more than 9 months. Upon receipt of the monitors it was found that two of the monitors were faulty. One displayed the error "failure" during calibration and the other calibrated but displayed no reading during test mode. The third monitor did successfully calibrate using 20ppm CO and 3 tests were performed with the same gas giving the readings 18, 20 & 19. This monitor was calibrated at a temperature of 24ºC.

As only one monitor was functioning the test could only be performed with a sample of one. This monitor was placed in Bedfont's in-house Astell Eurotherm chamber, to be tested at five set temperatures ranging from 0oC to 50oC in 10o increments. The monitor was left at the set temperature for 1 hour then removed for a brief period of time and tested with three different gas levels (20, 50, 100 ppm CO). After all concentrations were tested the monitor was placed back in the chamber at the next set temperature for 1 hour and the process was repeated.

Temperature	Gas Level (ppm)	Monitor Reading (ppm)
0	20	10
	50	29
	100	82
10	20	14
	50	32
	100	79
20	20	16
	50	38
	100	76
30	20	21
	50	52
	100	90
40	20	21
	50	51
	100	90

From the results shown above it can be seen that the monitor isn't accurate at the working temperature range of 15 – 25C stated in the product manual. When taken to 30C (which can easily be achieved at certain times of the year) the readings are actually more accurate which conflicts with the products specification. The variation in readings is almost certainly due to the poor temperature stability of the industrial grade sensor that is used in the Senko unit.
Overall the monitor is unstable in general, most likely due to the poor quality of sensor combined with incorrect calculations in the monitor's firmware.

Mouth piece and filter

The poorly copied Senko version of the Bedfont piCO⁺ D-mouth piece, non return valve and filter encourages incorrect use and poor cross infection control. See annex 2

CE Marking:

The monitor clearly displays a CE mark on the rear label but with no corresponding notified body number. The manual claims the monitor can diagnose CO poisoning, this will make the unit a medical device which will require a notified body number. There is nothing in the manual describing its CE mark so customers can only assume the product has been approved by a notified body.

Conversion from ppm CO to %COHb

Another interesting finding is that whilst testing the two monitors there was a discrepancy found between conversion from ppm CO to %COHb. Bedfont Scientific Ltd use a clinically proven ppm to %COHb conversion cited in 'M. J. Jarvis et al (1986) Low Cost Carbon Monoxide Monitors in Smoking Assessment. Thorax, 41, 886-887'. We are unaware of the clinical data that UBLOW have used for their COHb conversion, if any.

This discrepancy is shown below:

Senko BMC-2000	20ppm 3.2 %COHb	50ppm 8.0%COHb
piCO⁺ Smokerlyzer	20ppm 3.8%COHb	50ppm 8.6%COHb

Conclusion

Having been compared with a leading Breath Carbon Monoxide unit that has been on the market for a number of years and that has been perfected from its predecessors. It should be said that the BMC-2000 is not a suitable device for detecting breath Carbon Monoxide and is mainly let down by in-accuracy and inconsistency compared to other products out on the market not to mention unreliability. Its major flaw is its high cross sensitivity to hydrogen which will cause noticeable high readings in practical use.
Its D-Piece like design is also flawed in the fact that it is not airtight and is open to infection control risk.

In summary

The Senko BMC-2000 CO monitor suffers from the following:-
a) Very poor reliability.
b) Poor zero stability and zeroing.
c) Poor calibration stability due to temperature change.
d) Very high cross sensitivity to hydrogen leading to miss diagnosis.
e) Poor sensor signal to ratio 3 times worse than piCO⁺ leadindg to excessive noise(jitter in readings).
f) D-piece/valve and filter poorly implemented(/copied?) and open to user abuse not to mention poor infection control.
g) Senko sensor SS1128 has low gas diffusion characteristics favouring hydrogen over CO. Its working range is too large leading to low electrical output and requiring significant averaging(this appeared not to have been implemented to any great extent).

One comes to only one conclusion from the above that the Senko BMC-2000 CO monitor should not be sold or used in the UK/EU for medical smoking cessation applications.

Annex 1

Feedback from known BMC-2000 users:

April Drury - Stop Smoking Support Administrator - Central Essex Community Services:

"The BMC-2000 monitors were giving very high readings and were not reliable"

Rosemary Tooms - Norfolk Stop Smoking Service:

"The main problem was that the advisers could not rely on the readings as there was no consistency with them."

Alan Elgar – Service Manager - Portsmouth Stop Smoking Service:

"We initially had a demonstration of the monitors and they looked very good and simple to use. So we ordered one to trial them for a month or so. It proved to be ok for this period so we placed a larger order. These were all very unreliable giving readings that were out by as much as 10 or 20 ppm often showing non-smokers as smokers which can be de-motivating. The BMC-2000 representative came out to see us several times I think as he was sure there was a simple problem that could be solved. After some time he concluded that the problem was that we needed to 'zero-calibrate' the monitors each time we used them, this was not made clear in the demonstration and I have to say this would not be something that surgeries or pharmacists would be happy to do (or would even remember to do!); therefore the monitors are of no use to us except as a trade in! Most have not been used. I would not buy anymore BMC-2000.

Annex 2

D-Pieces

Upon a closer thorough examination it can be confirmed that the two D-Pieces are very similar by design and dimensions. The main difference is that the Senko D-Piece isn't sonically welded; it is in fact two separate pieces loosely clipped together. This is so the filter inside can easily be changed but sacrifices the airtight capabilities of the moulding and creating air passages around the filter which provides bad infection control.

Another noticeable difference is the increments on the mouthpiece shaft. It can only be assumed that these increments were placed there so the Senko D-Piece is compatible with multiple mouthpieces existing on the market.

The Senko D-Piece also implements a clip design at the exhaust end like the Bedfont D-Piece. The Senko D-piece has two of these clips and creates a good contact with the BMC monitor. When removing the D-Piece from the BMC-2000 it was found that a couple of times the D-Piece did actually separate into its two halves while trying to remove it, leaving the exhaust still inside the monitor. This also opened the filter chamber which means the user would have to touch the contaminated chamber to put the D-Piece back together. The Senko D-Piece does have a one way valve in place (also on the Bedfont D-Piece) to prevent bacteria from leaving the chamber but when separated the valve fails to do this causing potential infection for the user.

The filter itself is of very similar design to the one in the Bedfont D-Piece. When examined it was found that the material appears to be of the same design and build, The main difference is the diameter of the filter was noticeably smaller and far less dense than the Bedfont filter. Being smaller as well it also presents problems with infection control with the possibility of bacteria following the airways around the filter and into the monitor. The filter is being sent for testing to see if it has the same bacteria prevention as the Bedfont filter. The results will be included in this report at a later date.

The exhaust of the Senko D-Piece is also larger than the Bedfont D-Piece. With the addition of a second clip this means more airflow would be lost through the clips and this should incur a smaller exhaust hole. Being larger it could be assumed that the flow rate into the monitor would be lower but it was noticeably harder to blow through the Senko D-Piece then the Bedfont one. The only explanation for this must be the combination of the filter and one way valve inside the Senko D-Piece.

The above paragraphs state the main difference between the two D-Piece's but being differences they are still very similar. The biggest overall difference is the Senko D-Piece has a lot of problems with infection control compared to the Bedfont D-Piece.