

Table 1. Agreement Between the Data From Cluster 1 and  $P_{aCO_2}$ \*

Cluster	Nasal Cannula Group		Face Mask Group	
	$P_{aCO_2}$ 38.8 ± 2.3 mmHg (8 patients) Number of Capnograms in the Cluster	$P_{ETCO_2}$ (mmHg)	$P_{aCO_2}$ 43.8 ± 4.7 mm Hg (8 patients) Number of Capnograms in the Cluster	$P_{ETCO_2}$ (mmHg)
1	19 ± 11	35 ± 6	28 ± 15	32 ± 4
2	17 ± 5	33 ± 8	17 ± 7	30 ± 4
3	19 ± 8	30 ± 10	22 ± 6	26 ± 6
4	21 ± 8	27 ± 11	24 ± 10	26 ± 5
5	13 ± 8	23 ± 12	19 ± 10	20 ± 6

\*Each row corresponds to a cluster, including the mean ± SD of the 8 patients. A total of 1,586 capnograms were analysed: 801 in the nasal-cannula group, 785 in the face-mask group. Cluster 1 represents the nearest shape to the normal capnogram.

$P_{ETCO_2}$  = partial pressure of end-tidal carbon dioxide (Data from Reference 3.)

creating a  $P_{ETCO_2}$  measured value is drastically displaced.

From our side, this has led to an intelligent analytical procedure that we call "InCAP," which groups waveforms into clusters.<sup>3</sup> The cluster that most closely agrees with the normal capnogram is used for calculating  $P_{ETCO_2}$ . This analysis system provides considerably better agreement between the data from cluster 1 and the  $P_{aCO_2}$  value. The problematic nature of the conventional analysis of capnometers for the  $P_{ETCO_2}$  value is underscored by the form and number of capnograms recorded during spontaneous respiration. Table 1 shows the improved agreement, represented by the curves after grouping into 5 clusters (taken from 3). Furthermore, it is clear that the gas sampling is more effective with Oridion's oral/nasal cannula system than with a face mask. This effect could not be deduced from the data we presented.<sup>4</sup>

We stress that the analysis of gas samples is much more complex for patients breathing spontaneously than for patients undergoing artificial ventilation. Here one should not so much push the technique to the forefront, but should rather point out that alternative assessment procedures should be offered.

We thank Dr Lain for bringing this subject to the discussion table.

**Hartmut Gehring MD**  
on behalf of the all authors  
Department of Anesthesiology  
University Clinic of  
Schleswig-Holstein  
Luebeck, Germany

The authors report no conflict of interest related to the content of this letter.

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#### Spirometer Calibration Check Procedures

AS A READER OF *RESPIRATORY CARE* journal for many years and an advocate of that organ as a quality, peer-reviewed journal, I feel that I have to draw my professional concerns to your attention about the article by Pérez-Padilla et al, "The Long-Term Stability of Portable Spirometers Used in a

Multinational Study of the Prevalence of Chronic Obstructive Pulmonary Disease."<sup>1</sup>

Pérez-Padilla et al conclude that, "In these 70 EasyOne spirometers, neither calibration nor linearity changed during the study. Such calibration stability is a valuable feature in spirometry surveys and in the clinical setting." While calibration stability may be an admirable feature, there is absolutely no evidence in the Pérez-Padilla et al paper to support the conclusion that linearity did not change during the study. Pérez-Padilla et al performed a daily calibration check on each spirometer, using one of a number of 3-L syringes. This is simply a one-point calibration verification. How can a one-point measurement be considered a linearity check? For all Pérez-Padilla et al know, the response of each device theoretically could well have been alinear, and they would not have detected the alinearity. Those of us who have spent much of our professional lives working to improve quality assurance in pulmonary-function-test equipment know that a one-point verification is of extremely limited value. Further, there are many documented instances of spirometers that passed a calibration verification and then proceeded to give incorrect readings under clinical measurement conditions. That is why good laboratory practice calls for the use of physio-

logical controls, as supported by most professional societies around the world. One has to question, therefore, why Pérez-Padilla et al chose not to include any physiological controls in their study.

It is also noticeable that Pérez-Padilla et al chose only to use the American Thoracic Society's 1994 calibration protocol,<sup>2</sup> which was verification at a single flow rate, rather than the multi-point method recommended in the 2005 spirometry standard from the American Thoracic Society and European Respiratory Society.<sup>3</sup> Did Pérez-Padilla et al know that the EasyOne spirometer does not meet the requirement of the multi-point method in the 2005 standard? Why did they not mention this in the paper?

Unfortunately, the Pérez-Padilla et al paper shows a particular brand of spirometer in a good light. It is not my intention to comment on whether the device is a good one or a poor one, but instead simply to point out that publishing articles with flawed methods and incorrect conclusions can put a device in either a positive or negative light, which could have an important effect on the sales of that manufacturer. To give a misleading impression reflects badly upon what has up until now, in my opinion, been a revered journal.

#### Alan J Moore

Respiratory Physiology Service  
Department of Thoracic Medicine  
City Hospital  
Birmingham, United Kingdom

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#### *The authors respond:*

Mr Moore is correct that we did not test daily linearity, as recommended in the 2005 American Thoracic Society/European Respiratory Society (ATS-ERS) standard<sup>1</sup> (3 syringe injections, with different syringe-emptying speeds). As we described in our paper,<sup>2</sup> we performed one 3-L daily calibration check during the survey, which took place during 2003 and 2004. The available ATS standards were from 1994.<sup>3</sup> However, at the end of the survey, we observed that 3-L calibration checks were not done at one single flow, (as Mr Moore suggested), but with a wide variety of syringe flows (see Fig. 2 in our paper<sup>2</sup>). The peak flows we obtained during the syringe injections in 5% of the calibration checks were higher than 8 L/s (maximum 9.8 L/s) and in 5% of the calibration checks were lower than 2.2 L/s (minimum 0.4 L/s). But that wide range of flows did not significantly influence the measured volume, as can be seen in our Figure 2 and as described in the text. That the flow did not significantly affect the volume requires linearity, at least in that range of calibration flows, and is a piece of information available in our survey and maybe in others, with one syringe injection per day. Of course, the spirometers were not tested with all the flows shown in our Figure 2, but each spirometer had a variety of injection flows (mean flow range  $5.9 \pm 2.0$  L/s), applied on different days during the survey, and had correct volumes. This is the sense in which we used the term “linearity,” and not that described in the 2005 ATS-ERS standards.<sup>3</sup> Re-

cently, Walters et al published results similar to ours.<sup>4</sup>

We communicated our experience with 70 EasyOne spirometers during a survey done house-by-house, following a strict quality-control protocol. We have no doubt that other handheld spirometers can have at least a similar performance to the EasyOne spirometers we reported on. Researchers experienced in the long-term use of other devices should publish their results to provide potential users with this valuable information. Long-term calibration stability, the main issue in our paper, is a necessity if we want to expand the use of spirometry, especially in general practice.

Recently we collected 47 of the EasyOne spirometers used in the survey (in Mexico City, Montevideo, Sao Paulo, and Santiago) and tested their flow linearity with a flow-volume calibrator (FVC 3000, Jones Medical Instrument, Oak Brook, Illinois), with 17 flow points, ranging from  $< 1$  L/s to 16 L/s. The remaining 10 spirometers were not tested: 3 were out of order and 7 were unavailable. This calibration was after 2–3 years of use. The overall concordance correlation coefficient<sup>5</sup> between the syringe and the calibrator-measured flow was 0.995 (95% confidence interval 0.994–0.996) and the 95% limits of agreement<sup>6</sup> were between  $-0.431$  and  $0.663$  L/s. The calibration of 13 additional spirometers used in Caracas was adequate when tested with a 3-L syringe and 3 different flows, as required by current standards.

Finally, as we stated in the paper, none of the authors has a commercial relationship with the manufacturer of the EasyOne spirometer, so none of us will benefit if EasyOne sales increase.

#### Rogelio Pérez-Padilla MD

on behalf of the  
PLATINO Study Group  
Instituto Nacional de Enfermedades  
Respiratorias  
Distrito Federale  
Mexico City, Mexico