LETTERS TO THE EDITOR

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

REFERENCES

1. Operating instructions Microcap/Microcap
Plus. Oridion Capnography. REF 005547.
Declaration of conformity. June 1, 1999.

2. Stein N. Postoperative überwachung des ga-
saustausches bei spontanatmenden pati-
enten - einschätzung durch kapnometrie und
pulsoxymetrie. Medical thesis, University
of Luebeck, 2006.

3. Gehring H. Intelligent analysis of capno-
grams in spontaneously breathing patients.
Anesthesiology 2005;103:A852.

C, Roth-Isegkeit A, Hütte M, Gehring H.
An evaluation of a transtcutaneous and an
end-tidal capnometer for noninvasive moni-
toring of spontaneously breathing patients.
Respir Care 2006;51(10):1162–1166.

Spirometer Calibration
Check Procedures

As a reader of Respiratory Care
journal for many years and an adva-
cate 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 Stabil-
ity of Portable Spirometers Used in a
Multinational Study of the Prevalence of
Chronic Obstructive Pulmonary
Disease.”

Pérez-Padilla et al conclude that, “In
these 70 EasyOne spirometers, neither
calibration nor linearity changed dur-
ding the study. Such calibration stabil-
ity 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
to support the conclusion that
linearity did not change during the
study. Pérez-Padilla et al performed a
daily calibration check on each spi-
rometer, using one of a number of 3-L
syringes. This is simply a one-point
verification. How can a one-point measure-
ment 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
noticed the alinearity. Those of us
who have spent much of our profes-
sional lives working to improve qual-
ity assurance in pulmonary-function-
test equipment know that a one-point
verification is of extremely limited
value. Further, there are many docu-
mented instances of spirometers that
passed a calibration verification and
then proceeded to give incorrect read-
ings under clinical measurement con-
ditions. That is why good laboratory
practice calls for the use of physio-

creating a PETCO2 measured value is

From our side, this has lead to an
intelligent analytical procedure that we
call “InCAP,” which groups wave-
forms into clusters.3 The cluster that
most closely agrees with the normal
capnogram is used for calculating
PaCO2. This analysis system provides
considerably better agreement be-
tween the data from cluster 1 and the
PaCO2 value. The problematic nature
of the conventional analysis of cap-
nometers for the PETCO2 value is un-
derscored by the form and number of
capnograms recorded during sponta-
eaneous respiration. Table 1 shows the
improved agreement, represented by
the curves after grouping into 5 clus-
ters (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.4

We stress that the analysis of gas sam-

Table 1. Agreement Between the Data From Cluster 1 and PaCO2*

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Nasal Cannula Group</th>
<th>Face Mask Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P_{aCO2} 38.8 ± 2.3 mmHg (8 patients)</td>
<td>P_{aCO2} 43.8 ± 4.7 mmHg (8 patients)</td>
</tr>
<tr>
<td></td>
<td>Number of Capongrams in the Cluster</td>
<td>Number of Capongrams in the Cluster</td>
</tr>
<tr>
<td>1</td>
<td>19 ± 11</td>
<td>35 ± 6</td>
</tr>
<tr>
<td>2</td>
<td>17 ± 5</td>
<td>33 ± 8</td>
</tr>
<tr>
<td>3</td>
<td>19 ± 8</td>
<td>30 ± 10</td>
</tr>
<tr>
<td>4</td>
<td>21 ± 8</td>
<td>27 ± 11</td>
</tr>
<tr>
<td>5</td>
<td>13 ± 8</td>
<td>23 ± 12</td>
</tr>
<tr>
<td></td>
<td>P_{aCO2} (mmHg)</td>
<td>P_{aCO2} (mmHg)</td>
</tr>
<tr>
<td>1</td>
<td>28 ± 15</td>
<td>32 ± 4</td>
</tr>
<tr>
<td>2</td>
<td>17 ± 7</td>
<td>30 ± 4</td>
</tr>
<tr>
<td>3</td>
<td>22 ± 6</td>
<td>26 ± 6</td>
</tr>
<tr>
<td>4</td>
<td>24 ± 10</td>
<td>26 ± 5</td>
</tr>
<tr>
<td>5</td>
<td>19 ± 10</td>
<td>20 ± 6</td>
</tr>
</tbody>
</table>

*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.

PaCO2 = partial pressure of end-tidal carbon dioxide (Data from Reference 3.)
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, 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. 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.

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The author has current or has previously had consultancy agreements, or is receiving or has previously received educational sponsorship and/or hospitality, from the following manufacturers or vendors of spirometers or equipment related to pulmonary function testing: Beaver Medical PLC—UK, Clement Clarke International, Custo Med—Germany, Ferraris Cardiorespiratory, Medical International Research (MIR)—Rome, ndd Medical Technologies, and Viasys Healthcare.

REFERENCES


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 (3 syringe injections, with different syringe-emptying speeds). As we described in our paper, 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. 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). 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 ± 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.

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 between the syringe and the calibrator-measured flow was 0.995 (95% confidence interval 0.994–0.996) and the 95% limits of agreement 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.

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