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## **Value of gas exchange recording at home in children receiving noninvasive ventilation**

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## Value of gas exchange recording at home in children receiving noninvasive ventilation

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**Abstract**

Noninvasive positive pressure ventilation (NPPV) is preferentially performed at home.

The objectives of the study were to evaluate the feasibility of an overnight gas exchange recording at home and to compare recordings performed in the hospital and at home.

Twenty nine pairs of overnight gas exchange recordings during NPPV were performed at home and in the hospital in 11 children with neuromuscular disease and 13 children with other disorders treated with long term NPPV.

No technical problem occurred during the recordings performed at home and one pulse oximetry (SpO<sub>2</sub>) recording failed in the hospital. For the two groups, SpO<sub>2</sub> and transcutaneous carbon dioxide (PtcCO<sub>2</sub>) values did not differ significantly between the hospital and the home. However, correlations between SpO<sub>2</sub> and PtcCO<sub>2</sub> values obtained in the hospital and at home were better for mean values than for minimal and maximal values, and in patients with other disorders as compared to patients with neuromuscular disease.

Overnight gas exchange recordings with NPPV by a combined PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor are feasible at home and show results comparable to hospital recordings. Home PtcCO<sub>2</sub>/SpO<sub>2</sub> recordings may be integrated in the care of children treated with domiciliary NPPV and are associated with less disruption of family life and decreased health care costs.

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**Key words:** carbon dioxide, child, gas exchange, home, noninvasive positive pressure ventilation, pulse oximetry.

## Introduction

Noninvasive positive pressure ventilation (NPPV) is increasingly used in children presenting various diseases which may cause alveolar hypoventilation such as neuromuscular or lung disease, thoracic deformities, severe upper airway obstruction, or disorders of ventilatory control<sup>1,2</sup>. The main advantage of NPPV is that this technique may be used on demand, preferentially at night, with minimal disruption of normal life. After appropriate training of the family and caregivers, the majority of the children may be discharged home. Regular clinical and physiological follow up is necessary in order to adapt the NPPV modes and settings to the patient's clinical status and growth, and to check any side effect or respiratory or maxillofacial complication.

We have recently demonstrated the importance of a systematic overnight combined pulse oximetry (SpO<sub>2</sub>) and carbon dioxide (CO<sub>2</sub>) recording, even in patients in a stable condition without any symptom or sign of alveolar hypoventilation<sup>3</sup>. Indeed, 42% of 50 children who were well acclimatized to NPPV, without evidence of symptoms of sleep disordered breathing, were hypercapnic, defined by a maximal transcutaneous CO<sub>2</sub> (PtcCO<sub>2</sub>) value > 50 mmHg during sleep. Most importantly, this nocturnal hypercapnia was not associated with nocturnal hypoxemia, defined by a minimal SpO<sub>2</sub> < 92%, or abnormal daytime blood gases in 36% of the patients.

Repeated overnight hospitalizations are associated with disruption of family life and increased health care costs. Because of a general reduction in number of pediatric hospital beds, the transfer of selected, programmed, and well-organized activities or investigations from the hospital to the home is strongly encouraged. However, the feasibility, defined by the ability to obtain technically acceptable

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3 overnight recordings as well as the satisfaction of the parents with regard to their  
4 preference between hospital and home, and accuracy of these investigations  
5 performed in a home environment, should be evaluated before their wide spread use.  
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10 The aim of the present study was first to evaluate the feasibility of an overnight  
11 gas exchange recording by a combined transcutaneous CO<sub>2</sub> and pulse oximetry  
12 (PtcCO<sub>2</sub>/SpO<sub>2</sub>) monitor at home, and second to compare the results and costs of  
13 recordings performed in the hospital and at home in a cohort of stable children,  
14 treated at home with long term NPPV.  
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## 24 **Material and methods**

### 25 *Patients*

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34 Consecutive patients using nocturnal NPPV at home were enrolled during their  
35 routine follow up if 1) they were in a stable condition, with no respiratory exacerbation  
36 during the previous two months, 2) they were using NPPV for at least one month,  
37 and 3) they had no clinical symptoms of nocturnal hypoventilation such as frequent  
38 arousals, nocturnal agitation, or daytime fatigue and sleepiness. Exclusion criteria  
39 were 1) age less than one year because the ear clip of the PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor is  
40 too large for small infants <sup>3</sup>, 2) ear aplasia or hypoplasia for the same technical  
41 reasons <sup>3</sup>, 3) dark skin because of inaccurate SpO<sub>2</sub> values, as has been observed  
42 with other devices <sup>4</sup>, 4) impossibility to perform the hospital and home recording  
43 within one month, and 5) any change in the respiratory and/or clinical status of the  
44 patient.  
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3 All the parents, and if possible the patients, gave informed written consent for  
4 the study which was approved by the local ethical committee.  
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#### 10 *Overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> recording*

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15 Two overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> recordings were performed in a random order  
16 with the SenTec Digital Monitor (software version SMB SW-V06.10; MPB SW-  
17 V04.03) and the V-Sign™ Sensor which was applied to the earlobe with a dedicated  
18 Ear Clip (SenTec AG, Therwil, Switzerland). This fully digital sensor combines the  
19 elements of an electrochemical Severinghaus-type CO<sub>2</sub> tension sensor with the  
20 optical elements of conventional SpO<sub>2</sub> sensors, thus providing a noninvasive and  
21 continuous PtcCO<sub>2</sub> and SpO<sub>2</sub> monitoring. The sensor is warmed to a constant  
22 surface temperature of 42°C to improve local arterialization of the measurement site.  
23 This PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor has been validated for adults<sup>5</sup> and for children in our  
24 laboratory<sup>3</sup>.  
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38 The two overnight SpO<sub>2</sub> and PtcCO<sub>2</sub> recordings were started at the patient's  
39 usual bedtime. In the hospital, care was taken to respect the patient's sleep. Prior to  
40 the application of the sensor to the patient, the sensor was prepared by the nurse in  
41 the hospital and the technician at home and calibrated as per the manufacturer  
42 recommendations. The sensor was then applied by the nurse or the technician to the  
43 patient's earlobe for 15 minutes, until the stabilization of the PtcCO<sub>2</sub> and SpO<sub>2</sub>  
44 values. Monitoring was then performed during at least 6 hours. In the hospital, sleep  
45 with NPPV as well as the correct positioning of the nasal mask and the ear clip was  
46 regularly checked by the attending nurse during the night. At home, the parents were  
47 asked to check these elements before they went to sleep and eventually a second  
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3 time during the night. The parents were taught how to remove the ear clip at  
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6 awakening.

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8 After the two recordings, the parents were asked: "Did your child sleep better  
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10 in the hospital or at home ?" and "Do you prefer a recording performed in the hospital  
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12 or at home ?".  
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### 14 15 16 17 *Analysis of the nocturnal gas exchange*

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20 For each overnight sleep study, the following data were calculated: duration of  
21  
22 recording, mean and minimal SpO<sub>2</sub>, percentage of night time spent with a SpO<sub>2</sub> >  
23  
24 95%, between 94 and 95%, between 93 and 92%, and < 92%; mean and maximal  
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26 PtcCO<sub>2</sub>, % of night time spent with a PtcCO<sub>2</sub> > 50 mm Hg and ≤ 50 mmHg.  
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### 34 *Statistical analysis*

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38 The patients were separated into two groups; patients with neuromuscular  
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40 diseases (n=11) and patients with other disorders (n=13). For each group and type of  
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42 recording (hospital and home), the median value of mean and minimal SpO<sub>2</sub> and of  
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44 mean and maximal PtcCO<sub>2</sub> was calculated because the values were not normally  
45  
46 distributed. Comparison between the home and hospital recordings was performed  
47  
48 by the Mann Whitney Rank Sum test.  
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53 Moreover, individual data were analyzed by plotting mean and minimal SpO<sub>2</sub>  
54  
55 and mean and maximal PtcCO<sub>2</sub> observed in the hospital against the values obtained  
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57 at home for each patient. Correlation between the values recorded at home and in  
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59 the hospital was performed using simple linear regression. Statistical analyses were  
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3 done using the SigmaStat (Systat Software Inc., San Jose, California). Values of  
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5  $p < 0.05$  were considered statistically significant.  
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## 8 9 10 **Results**

### 11 12 13 14 15 *Patients*

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20 Twenty four consecutive patients were included in the study with 5 patients  
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22 having 2 series of hospital and home recording more than 3 months apart. Four  
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24 patients with neuromuscular disease and one patient with another disorder had 2  
25  
26 pairs of recordings. The characteristics of the patients are given in Table 1.  
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### 29 30 31 32 *Feasibility of home recording*

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36 Of the 29 recordings performed at home, one recording was technically correct  
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38 but could not be analyzed because of an error on the date. The SpO<sub>2</sub> recording could  
39  
40 not be analyzed in another patient in the hospital but the PtcCO<sub>2</sub> recording was  
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42 exploitable. All the other recordings performed at home and in the hospital were  
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44 correct and could be analyzed.  
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### 50 51 *Comparison of home and hospital recordings*

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55 Despite randomization, only 4 recordings were initially performed at home and  
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57 25 in the hospital. The median delay between the hospital and home recordings was  
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59 11 (range 3-28) days in patients with neuromuscular disease and 7 (2-30) days in  
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3 patients with other disorders (p not significant (NS)). The median duration of the  
4  
5 overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> recording was comparable at home (503 minutes, range 360-  
6  
7 609) and in the hospital (560 minutes, range 231-688, p=NS). Table 2 shows that the  
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9 SpO<sub>2</sub> and PtcCO<sub>2</sub> values did not differ significantly between the hospital and the  
10  
11 home. Moreover, the results were not different between the patients with  
12  
13 neuromuscular disease and those with other disorders. Figure 1 shows the  
14  
15 correlation of mean and minimal SpO<sub>2</sub> values in the hospital and at home for each  
16  
17 patient. The correlation of mean SpO<sub>2</sub> in the hospital and at home was significant for  
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19 patients with other disorders (r=0.608, p=0.028) but not for patients with  
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21 neuromuscular diseases (r=0.494, p=0.061). For minimal SpO<sub>2</sub>, no significant  
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23 correlation was observed for the two groups of patients (r=0.340, p=0.215 and  
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25 r=0.547, p=0.053 for patients with neuromuscular disease and other diseases,  
26  
27 respectively). Interestingly, 4 patients had a minimal SpO<sub>2</sub> below 90% in the hospital  
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29 but not at home, and conversely, 9 patients had a minimal SpO<sub>2</sub> below 90% at home  
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31 but not in the hospital. Figure 2 shows the percentage of time spent with the different  
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33 SpO<sub>2</sub> ranges in the two groups of patients. Again, no significant differences were  
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35 observed between the recordings performed in the hospital and at home in both  
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37 groups of patients (t-test, all NS).  
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46 Figure 3 shows the correlation of mean and maximal PtcCO<sub>2</sub> values in the  
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48 hospital and at home for each patient. The correlation of mean PtcCO<sub>2</sub> in the hospital  
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50 and at home was significant in the two groups of patients (r=0.647, p=0.009, and  
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52 r=0.562, p=0.037, for patients with neuromuscular disease and patients with other  
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54 disorders, respectively). The correlation for maximal PtcCO<sub>2</sub> was significant for  
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56 patients with other diseases (r=0.636, p=0.014) but not for patients with  
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58 neuromuscular diseases (r=0.417, p=0.122). Figure 4 shows the percentage of time  
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3 spent with the different PtcCO<sub>2</sub> ranges in the two groups of patients. Again, no  
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5 significant differences were observed between the recordings performed in the  
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7 hospital and at home in both groups of patients (t-test, all NS).  
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10 According to the parents, they all found that their child slept better at home.  
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12 With regard to the satisfaction of the parents, they all preferred the recording at  
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14 home.  
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17 The cost of one overnight hospitalization in our pediatric pulmonology unit is  
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19 1029,00 euros. This cost should be compared to 2 technician home visits, one in the  
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21 evening at the child's bedtime and one in the morning (2 x 25,16 = 50,32 euros). The  
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23 cost of the transport has to be added to this amount; the French health care system  
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25 reimburses 20,09 euros per visit, which make a total of 90,50 euros per home  
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27 monitoring.  
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31 The 5 patients who had persistent alveolar hypoventilation during both  
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33 recordings, as defined by a maximal PtcCO<sub>2</sub> value > 50 mm Hg and/or a minimal  
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35 SpO<sub>2</sub> value < 90% had one or several interventions in the hospital such as the  
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37 change of the ventilatory settings or mode, the addition of an abdominal girdle or a  
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39 chin strap, and/or the change of the interface. An overnight gas exchange control  
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41 was performed systematically before discharge.  
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## 48 Discussion

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53 This study is the first to show the feasibility of overnight PtcCO<sub>2</sub>/SpO<sub>2</sub>  
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55 recording in a group of children over the age of 4 years, treated at home with long  
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57 term NPPV. Twenty eight of the 29 (97%) recordings were analyzable when a trained  
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59 technician installed the equipment at home and instructed the parents how to  
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3 supervise the recording and remove the ear clip in the morning. SpO<sub>2</sub> and PtcCO<sub>2</sub>  
4 values did not differ significantly between the hospital and the home. However, a  
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6 better correlation between hospital and home values was observed for mean values  
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8 as compared to minimal and maximal values, and in patients with other disorders as  
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10 compared to patients with neuromuscular disease. Of note, parent's preference and  
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12 cost favored home recording.  
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17 Different types of monitoring are routinely performed at home in children such  
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19 as cardiorespiratory monitoring in children at risk for sudden infant death syndrome <sup>6-</sup>  
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21 <sup>8</sup>, pH monitoring for the diagnosis of gastro-oesophageal reflux <sup>9</sup>, blood pressure  
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23 monitoring <sup>10</sup>, EEG monitoring <sup>11,12</sup>, polygraphy for the screening of obstructive sleep  
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25 apnea <sup>13-16</sup>, and even telemonitoring of exhaled nitric oxide for asthmatic children <sup>17</sup> .  
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29 We were initially relatively reluctant to the use of the PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor at  
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31 home because the device requires a correct calibration, the Sign™ Sensor is quite  
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33 fragile, and the correct positioning of the ear clip with the head gear for the NPPV  
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35 may not be easy in a young child. Technically acceptable recordings were obtained  
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37 in 75% to 99% of the cases during the above mentioned studies <sup>6-17</sup>. However, no  
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39 technical problem occurred at home during any of the 29 recordings in the present  
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41 study. This may be explained by the adequate training of the technicians of the home  
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43 care organization who installed the PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor on the child at bed time,  
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45 which requires thus a home visit outside office hours. However, this procedure  
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47 seemed for us the guarantee of success.  
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53 Correlation between hospital and home recordings was better for mean SpO<sub>2</sub>  
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55 and PtcCO<sub>2</sub> values than for minimal SpO<sub>2</sub> and maximal PtcCO<sub>2</sub>. This is easy  
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57 understandable because a mean value is calculated over the whole recording period,  
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59 and it thus less variable than an extreme value. We have no clear explanation for the  
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3 better correlation between hospital and home SpO<sub>2</sub> and PtcCO<sub>2</sub> values in patients  
4 with other diseases as compared to patients with neuromuscular diseases. A  
5 possible explanation could be that patients with other diseases, who are  
6 predominantly patients with upper airway obstruction, are more stable than patients  
7 with neuromuscular disease. In practice, minimal and maximal values should be  
8 interpreted with more caution than mean values when comparing hospital and home  
9 recordings.

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20 A limitation of our study is the lack of data on objective sleep quality. Improved  
21 nocturnal gas exchange is not obligatory associated with better sleep quality<sup>18</sup>. A  
22 parallel improvement in nocturnal gas exchange and sleep architecture during NPPV  
23 has been observed in adult patients in two studies<sup>19,20</sup> but not in two others<sup>21,22</sup>. A  
24 study establishing home polysomnography norms for children showed better sleep  
25 quantity and quality at home<sup>14</sup>. Another study compared 2 sleep studies performed  
26 at home and in the hospital in 21 children aged 2-12 years with possible obstructive  
27 sleep apnea<sup>13</sup>. Sleep efficiency was significantly greater and the arousal index was  
28 significantly lower at home than in the laboratory. Finally, a study that compared  
29 blood pressure monitoring at home and in the hospital also observed significant lower  
30 diastolic blood pressure at home<sup>10</sup>, which supports a lower stress level when  
31 children are in their home environment.

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48 Even if we observed a trend for better results during home recordings, this  
49 was not significant (Table 2). We may thus conclude that home recordings are  
50 feasible and may show results comparable to those obtained at **hospital**, justifying  
51 their integration in the routine management in children receiving long term NPPV. A  
52 regular and systematic check of the ventilator settings and circuit, the interface and  
53 its possible side effects, and also the potential problems that may occur during NPPV  
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3 such as air leaks, are, to our opinion, important to document during an overnight  
4 observation in the hospital. As such, we would recommend a combination of home  
5 and hospital recordings, not only for the patient's and parent's comfort but also with  
6 regard to the familial and financial burden. Because individual data may be better in  
7 the home or in the hospital, we would recommend a change of NPPV settings or  
8 additional measures only in case of abnormal values in both conditions. **Those**  
9 **patients with an abnormal "in home" gas exchange should be referred for an "in**  
10 **hospital" titration study.**  
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22 In conclusion, overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> monitoring is feasible at home and  
23 shows comparable results to hospital recordings. Systematic and regular home  
24 monitoring, combined with regular hospital visits, is recommended in children treated  
25 at home with NPPV.  
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36 All the authors declare that they have no conflict of interest with the data presented in  
37 this manuscript.  
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## Legend of the figures

### Figure 1

Individual mean (left figure) and minimal (right figure) pulse oximetry ( $\text{SpO}_2$ ) values observed at home and in the hospital in patients with neuromuscular disease (black circles) and with other disorders (open circles).

For mean  $\text{SpO}_2$ , regression lines are represented (plain for patients with neuromuscular disease ( $r=0.494$ ,  $p=0.061$ ) and dashed for patients with other disorders ( $r=0.608$ ,  $p=0.028$ )). Several patients having similar  $\text{SpO}_2$  values, only 15 of the 28 spots are visible.

For minimal  $\text{SpO}_2$ , regression lines are represented (plain for patients with neuromuscular disease ( $r=0.340$ ,  $p=\text{NS}$ ) and dashed for patients with other disorders ( $r=0.547$ ,  $p=\text{NS}$ )). Two patients having similar  $\text{SpO}_2$  values, only 27 of the 28 spots are visible.

### Figure 2

Comparison of percentage of nocturnal recording time spent with a pulse oximetry ( $\text{SpO}_2$ )  $> 95\%$ , between 94 and 95%, between 93 and 92%, and  $< 92\%$  during the recordings performed in the hospital (black bars) and at home (grey bars).

### Figure 3

Individual mean (left figure) and maximal (right figure) transcutaneous carbon dioxide ( $\text{PtcCO}_2$ ) values observed at home and in the hospital in patients with neuromuscular disease (black circles) and with other disorders (open circles).

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3 For mean PtcCO<sub>2</sub>, regression lines are represented (plain for patients with  
4 neuromuscular disease (r=0.647, p=0.009) and dashed for patients with other  
5 disorders (r=0.564, p=0.037))  
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10 For maximal PtcCO<sub>2</sub>, regression lines are represented (plain for patients with  
11 neuromuscular disease (r=0.417, p=NS) and dashed for patients with other disorders  
12 (r=0.636, p=0.014).  
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17 Three patients having similar PtcCO<sub>2</sub> values, only 27 of the 29 spots are visible.  
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#### 20 21 22 **Figure 4**

23  
24 Comparison of percentage of nocturnal recording time spent with a PtcCO<sub>2</sub> > 50  
25 mmHg and ≤ 50 mmHg during the recordings performed in the hospital (black bars)  
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27 and at home (grey bars).  
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## Value of gas exchange recording at home in children receiving noninvasive ventilation

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**Running head:** Gas exchange during noninvasive ventilation

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**Abstract**

Noninvasive positive pressure ventilation (NPPV) is preferentially performed at home.

The objectives of the study were to evaluate the feasibility of an overnight gas exchange recording at home and to compare recordings performed in the hospital and at home.

Twenty nine pairs of overnight gas exchange recordings during NPPV were performed at home and in the hospital in 11 children with neuromuscular disease and 13 children with other disorders treated with long term NPPV.

No technical problem occurred during the recordings performed at home and one pulse oximetry (SpO<sub>2</sub>) recording failed in the hospital. For the two groups, SpO<sub>2</sub> and transcutaneous carbon dioxide (PtcCO<sub>2</sub>) values did not differ significantly between the hospital and the home. However, correlations between SpO<sub>2</sub> and PtcCO<sub>2</sub> values obtained in the hospital and at home were better for mean values than for minimal and maximal values, and in patients with other disorders as compared to patients with neuromuscular disease.

Overnight gas exchange recordings with NPPV by a combined PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor are feasible at home and show results comparable to hospital recordings. Home PtcCO<sub>2</sub>/SpO<sub>2</sub> recordings may be integrated in the care of children treated with domiciliary NPPV and are associated with less disruption of family life and decreased health care costs.

**Word count of the abstract:** 204

**Key words:** carbon dioxide, child, gas exchange, home, noninvasive positive pressure ventilation, pulse oximetry.

## Introduction

Noninvasive positive pressure ventilation (NPPV) is increasingly used in children presenting various diseases which may cause alveolar hypoventilation such as neuromuscular or lung disease, thoracic deformities, severe upper airway obstruction, or disorders of ventilatory control<sup>1,2</sup>. The main advantage of NPPV is that this technique may be used on demand, preferentially at night, with minimal disruption of normal life. After appropriate training of the family and caregivers, the majority of the children may be discharged home. Regular clinical and physiological follow up is necessary in order to adapt the NPPV modes and settings to the patient's clinical status and growth, and to check any side effect or respiratory or maxillofacial complication.

We have recently demonstrated the importance of a systematic overnight combined pulse oximetry (SpO<sub>2</sub>) and carbon dioxide (CO<sub>2</sub>) recording, even in patients in a stable condition without any symptom or sign of alveolar hypoventilation<sup>3</sup>. Indeed, 42% of 50 children who were well acclimatized to NPPV, without evidence of symptoms of sleep disordered breathing, were hypercapnic, defined by a maximal transcutaneous CO<sub>2</sub> (PtcCO<sub>2</sub>) value > 50 mmHg during sleep. Most importantly, this nocturnal hypercapnia was not associated with nocturnal hypoxemia, defined by a minimal SpO<sub>2</sub> < 92%, or abnormal daytime blood gases in 36% of the patients.

Repeated overnight hospitalizations are associated with disruption of family life and increased health care costs. Because of a general reduction in number of pediatric hospital beds, the transfer of selected, programmed, and well-organized activities or investigations from the hospital to the home is strongly encouraged. However, the feasibility, defined by the ability to obtain technically acceptable

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3 overnight recordings as well as the satisfaction of the parents with regard to their  
4 preference between hospital and home, and accuracy of these investigations  
5 performed in a home environment, should be evaluated before their wide spread use.  
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10 The aim of the present study was first to evaluate the feasibility of an overnight  
11 gas exchange recording by a combined transcutaneous CO<sub>2</sub> and pulse oximetry  
12 (PtcCO<sub>2</sub>/SpO<sub>2</sub>) monitor at home, and second to compare the results and costs of  
13 recordings performed in the hospital and at home in a cohort of stable children,  
14 treated at home with long term NPPV.  
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## 24 **Material and methods**

### 25 *Patients*

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34 Consecutive patients using nocturnal NPPV at home were enrolled during their  
35 routine follow up if 1) they were in a stable condition, with no respiratory exacerbation  
36 during the previous two months, 2) they were using NPPV for at least one month,  
37 and 3) they had no clinical symptoms of nocturnal hypoventilation such as frequent  
38 arousals, nocturnal agitation, or daytime fatigue and sleepiness. Exclusion criteria  
39 were 1) age less than one year because the ear clip of the PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor is  
40 too large for small infants <sup>3</sup>, 2) ear aplasia or hypoplasia for the same technical  
41 reasons <sup>3</sup>, 3) dark skin because of inaccurate SpO<sub>2</sub> values, as has been observed  
42 with other devices <sup>4</sup>, 4) impossibility to perform the hospital and home recording  
43 within one month, and 5) any change in the respiratory and/or clinical status of the  
44 patient.  
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3 All the parents, and if possible the patients, gave informed written consent for  
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5 the study which was approved by the local ethical committee.  
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10 *Overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> recording*  
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15 Two overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> recordings were performed in a random order  
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17 with the SenTec Digital Monitor (software version SMB SW-V06.10; MPB SW-  
18 V04.03) and the V-Sign™ Sensor which was applied to the earlobe with a dedicated  
19 Ear Clip (SenTec AG, Therwil, Switzerland). This fully digital sensor combines the  
20 elements of an electrochemical Severinghaus-type CO<sub>2</sub> tension sensor with the  
21 optical elements of conventional SpO<sub>2</sub> sensors, thus providing a noninvasive and  
22 continuous PtcCO<sub>2</sub> and SpO<sub>2</sub> monitoring. The sensor is warmed to a constant  
23 surface temperature of 42°C to improve local arterialization of the measurement site.  
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25 This PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor has been validated for adults<sup>5</sup> and for children in our  
26 laboratory<sup>3</sup>.  
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39 The two overnight SpO<sub>2</sub> and PtcCO<sub>2</sub> recordings were started at the patient's  
40 usual bedtime. In the hospital, care was taken to respect the patient's sleep. Prior to  
41 the application of the sensor to the patient, the sensor was prepared by the nurse in  
42 the hospital and the technician at home and calibrated as per the manufacturer  
43 recommendations. The sensor was then applied by the nurse or the technician to the  
44 patient's earlobe for 15 minutes, until the stabilization of the PtcCO<sub>2</sub> and SpO<sub>2</sub>  
45 values. Monitoring was then performed during at least 6 hours. In the hospital, sleep  
46 with NPPV as well as the correct positioning of the nasal mask and the ear clip was  
47 regularly checked by the attending nurse during the night. At home, the parents were  
48 asked to check these elements before they went to sleep and eventually a second  
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3 time during the night. The parents were taught how to remove the ear clip at  
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6 awakening.

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8 After the two recordings, the parents were asked: "Did your child sleep better  
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10 in the hospital or at home ?" and "Do you prefer a recording performed in the hospital  
11  
12 or at home ?".  
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### 14 15 16 17 *Analysis of the nocturnal gas exchange*

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20 For each overnight sleep study, the following data were calculated: duration of  
21  
22 recording, mean and minimal SpO<sub>2</sub>, percentage of night time spent with a SpO<sub>2</sub> >  
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24 95%, between 94 and 95%, between 93 and 92%, and < 92%; mean and maximal  
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26 PtcCO<sub>2</sub>, % of night time spent with a PtcCO<sub>2</sub> > 50 mm Hg and ≤ 50 mmHg.  
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### 33 34 *Statistical analysis*

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38 The patients were separated into two groups; patients with neuromuscular  
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40 diseases (n=11) and patients with other disorders (n=13). For each group and type of  
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42 recording (hospital and home), the median value of mean and minimal SpO<sub>2</sub> and of  
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44 mean and maximal PtcCO<sub>2</sub> was calculated because the values were not normally  
45  
46 distributed. Comparison between the home and hospital recordings was performed  
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48 by the Mann Whitney Rank Sum test.  
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53 Moreover, individual data were analyzed by plotting mean and minimal SpO<sub>2</sub>  
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55 and mean and maximal PtcCO<sub>2</sub> observed in the hospital against the values obtained  
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57 at home for each patient. Correlation between the values recorded at home and in  
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59 the hospital was performed using simple linear regression. Statistical analyses were  
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3 done using the SigmaStat (Systat Software Inc., San Jose, California). Values of  
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5  $p < 0.05$  were considered statistically significant.  
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## 8 9 10 **Results**

### 11 12 13 14 15 *Patients*

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20 Twenty four consecutive patients were included in the study with 5 patients  
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22 having 2 series of hospital and home recording more than 3 months apart. Four  
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24 patients with neuromuscular disease and one patient with another disorder had 2  
25  
26 pairs of recordings. The characteristics of the patients are given in Table 1.  
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### 29 30 31 32 *Feasibility of home recording*

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36 Of the 29 recordings performed at home, one recording was technically correct  
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38 but could not be analyzed because of an error on the date. The SpO<sub>2</sub> recording could  
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40 not be analyzed in another patient in the hospital but the PtcCO<sub>2</sub> recording was  
41  
42 exploitable. All the other recordings performed at home and in the hospital were  
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44 correct and could be analyzed.  
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### 50 51 *Comparison of home and hospital recordings*

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55 Despite randomization, only 4 recordings were initially performed at home and  
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57 25 in the hospital. The median delay between the hospital and home recordings was  
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59 11 (range 3-28) days in patients with neuromuscular disease and 7 (2-30) days in  
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3 patients with other disorders (p not significant (NS)). The median duration of the  
4  
5 overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> recording was comparable at home (503 minutes, range 360-  
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7 609) and in the hospital (560 minutes, range 231-688, p=NS). Table 2 shows that the  
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9 SpO<sub>2</sub> and PtcCO<sub>2</sub> values did not differ significantly between the hospital and the  
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11 home. Moreover, the results were not different between the patients with  
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13 neuromuscular disease and those with other disorders. Figure 1 shows the  
14  
15 correlation of mean and minimal SpO<sub>2</sub> values in the hospital and at home for each  
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17 patient. The correlation of mean SpO<sub>2</sub> in the hospital and at home was significant for  
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19 patients with other disorders (r=0.608, p=0.028) but not for patients with  
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21 neuromuscular diseases (r=0.494, p=0.061). For minimal SpO<sub>2</sub>, no significant  
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23 correlation was observed for the two groups of patients (r=0.340, p=0.215 and  
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25 r=0.547, p=0.053 for patients with neuromuscular disease and other diseases,  
26  
27 respectively). Interestingly, 4 patients had a minimal SpO<sub>2</sub> below 90% in the hospital  
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29 but not at home, and conversely, 9 patients had a minimal SpO<sub>2</sub> below 90% at home  
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31 but not in the hospital. Figure 2 shows the percentage of time spent with the different  
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33 SpO<sub>2</sub> ranges in the two groups of patients. Again, no significant differences were  
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35 observed between the recordings performed in the hospital and at home in both  
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37 groups of patients (t-test, all NS).  
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46 Figure 3 shows the correlation of mean and maximal PtcCO<sub>2</sub> values in the  
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48 hospital and at home for each patient. The correlation of mean PtcCO<sub>2</sub> in the hospital  
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50 and at home was significant in the two groups of patients (r=0.647, p=0.009, and  
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52 r=0.562, p=0.037, for patients with neuromuscular disease and patients with other  
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54 disorders, respectively). The correlation for maximal PtcCO<sub>2</sub> was significant for  
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56 patients with other diseases (r=0.636, p=0.014) but not for patients with  
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58 neuromuscular diseases (r=0.417, p=0.122). Figure 4 shows the percentage of time  
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3 spent with the different PtcCO<sub>2</sub> ranges in the two groups of patients. Again, no  
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5 significant differences were observed between the recordings performed in the  
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7 hospital and at home in both groups of patients (t-test, all NS).  
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10 According to the parents, they all found that their child slept better at home.  
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12 With regard to the satisfaction of the parents, they all preferred the recording at  
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14 home.  
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17 The cost of one overnight hospitalization in our pediatric pulmonology unit is  
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19 1029,00 euros. This cost should be compared to 2 technician home visits, one in the  
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21 evening at the child's bedtime and one in the morning (2 x 25,16 = 50,32 euros). The  
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23 cost of the transport has to be added to this amount; the French health care system  
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25 reimburses 20,09 euros per visit, which make a total of 90,50 euros per home  
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27 monitoring.  
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31 The 5 patients who had persistent alveolar hypoventilation during both  
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33 recordings, as defined by a maximal PtcCO<sub>2</sub> value > 50 mm Hg and/or a minimal  
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35 SpO<sub>2</sub> value < 90% had one or several interventions in the hospital such as the  
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37 change of the ventilatory settings or mode, the addition of an abdominal girdle or a  
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39 chin strap, and/or the change of the interface. An overnight gas exchange control  
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41 was performed systematically before discharge.  
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## 48 Discussion

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53 This study is the first to show the feasibility of overnight PtcCO<sub>2</sub>/SpO<sub>2</sub>  
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55 recording in a group of children over the age of 4 years, treated at home with long  
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57 term NPPV. Twenty eight of the 29 (97%) recordings were analyzable when a trained  
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59 technician installed the equipment at home and instructed the parents how to  
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3 supervise the recording and remove the ear clip in the morning. SpO<sub>2</sub> and PtcCO<sub>2</sub>  
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5 values did not differ significantly between the hospital and the home. However, a  
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7 better correlation between hospital and home values was observed for mean values  
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9 as compared to minimal and maximal values, and in patients with other disorders as  
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11 compared to patients with neuromuscular disease. Of note, parent's preference and  
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13 cost favored home recording.  
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17 Different types of monitoring are routinely performed at home in children such  
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19 as cardiorespiratory monitoring in children at risk for sudden infant death syndrome <sup>6-</sup>  
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21 <sup>8</sup>, pH monitoring for the diagnosis of gastro-oesophageal reflux <sup>9</sup>, blood pressure  
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23 monitoring <sup>10</sup>, EEG monitoring <sup>11,12</sup>, polygraphy for the screening of obstructive sleep  
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25 apnea <sup>13-16</sup>, and even telemonitoring of exhaled nitric oxide for asthmatic children <sup>17</sup> .  
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29 We were initially relatively reluctant to the use of the PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor at  
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31 home because the device requires a correct calibration, the Sign™ Sensor is quite  
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33 fragile, and the correct positioning of the ear clip with the head gear for the NPPV  
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35 may not be easy in a young child. Technically acceptable recordings were obtained  
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37 in 75% to 99% of the cases during the above mentioned studies <sup>6-17</sup>. However, no  
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39 technical problem occurred at home during any of the 29 recordings in the present  
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41 study. This may be explained by the adequate training of the technicians of the home  
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43 care organization who installed the PtcCO<sub>2</sub>/SpO<sub>2</sub> monitor on the child at bed time,  
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45 which requires thus a home visit outside office hours. However, this procedure  
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47 seemed for us the guarantee of success.  
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53 Correlation between hospital and home recordings was better for mean SpO<sub>2</sub>  
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55 and PtcCO<sub>2</sub> values than for minimal SpO<sub>2</sub> and maximal PtcCO<sub>2</sub>. This is easy  
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57 understandable because a mean value is calculated over the whole recording period,  
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59 and it thus less variable than an extreme value. We have no clear explanation for the  
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3 better correlation between hospital and home SpO<sub>2</sub> and PtcCO<sub>2</sub> values in patients  
4 with other diseases as compared to patients with neuromuscular diseases. A  
5 possible explanation could be that patients with other diseases, who are  
6 predominantly patients with upper airway obstruction, are more stable than patients  
7 with neuromuscular disease. In practice, minimal and maximal values should be  
8 interpreted with more caution than mean values when comparing hospital and home  
9 recordings.

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20 A limitation of our study is the lack of data on objective sleep quality. Improved  
21 nocturnal gas exchange is not obligatory associated with better sleep quality<sup>18</sup>. A  
22 parallel improvement in nocturnal gas exchange and sleep architecture during NPPV  
23 has been observed in adult patients in two studies<sup>19,20</sup> but not in two others<sup>21,22</sup>. A  
24 study establishing home polysomnography norms for children showed better sleep  
25 quantity and quality at home<sup>14</sup>. Another study compared 2 sleep studies performed  
26 at home and in the hospital in 21 children aged 2-12 years with possible obstructive  
27 sleep apnea<sup>13</sup>. Sleep efficiency was significantly greater and the arousal index was  
28 significantly lower at home than in the laboratory. Finally, a study that compared  
29 blood pressure monitoring at home and in the hospital also observed significant lower  
30 diastolic blood pressure at home<sup>10</sup>, which supports a lower stress level when  
31 children are in their home environment.

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48 Even if we observed a trend for better results during home recordings, this  
49 was not significant (Table 2). We may thus conclude that home recordings are  
50 feasible and may show results comparable to those obtained at hospital, justifying  
51 their integration in the routine management in children receiving long term NPPV. A  
52 regular and systematic check of the ventilator settings and circuit, the interface and  
53 its possible side effects, and also the potential problems that may occur during NPPV

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3 such as air leaks, are, to our opinion, important to document during an overnight  
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5 observation in the hospital. As such, we would recommend a combination of home  
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7 and hospital recordings, not only for the patient's and parent's comfort but also with  
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9 regard to the familial and financial burden. Because individual data may be better in  
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11 the home or in the hospital, we would recommend a change of NPPV settings or  
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13 additional measures only in case of abnormal values in both conditions. Those  
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15 patients with an abnormal "in home" gas exchange should be referred for an "in  
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17 hospital" titration study.  
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22 In conclusion, overnight PtcCO<sub>2</sub>/SpO<sub>2</sub> monitoring is feasible at home and  
23  
24 shows comparable results to hospital recordings. Systematic and regular home  
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26 monitoring, combined with regular hospital visits, is recommended in children treated  
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28 at home with NPPV.  
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### 33 **Acknowledgments**

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36 All the authors declare that they have no conflict of interest with the data presented in  
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38 this manuscript.  
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## Legend of the figures

### Figure 1

Individual mean (left figure) and minimal (right figure) pulse oximetry ( $\text{SpO}_2$ ) values observed at home and in the hospital in patients with neuromuscular disease (black circles) and with other disorders (open circles).

For mean  $\text{SpO}_2$ , regression lines are represented (plain for patients with neuromuscular disease ( $r=0.494$ ,  $p=0.061$ ) and dashed for patients with other disorders ( $r=0.608$ ,  $p=0.028$ )). Several patients having similar  $\text{SpO}_2$  values, only 15 of the 28 spots are visible.

For minimal  $\text{SpO}_2$ , regression lines are represented (plain for patients with neuromuscular disease ( $r=0.340$ ,  $p=\text{NS}$ ) and dashed for patients with other disorders ( $r=0.547$ ,  $p=\text{NS}$ )). Two patients having similar  $\text{SpO}_2$  values, only 27 of the 28 spots are visible.

### Figure 2

Comparison of percentage of nocturnal recording time spent with a pulse oximetry ( $\text{SpO}_2$ )  $> 95\%$ , between 94 and 95%, between 93 and 92%, and  $< 92\%$  during the recordings performed in the hospital (black bars) and at home (grey bars).

### Figure 3

Individual mean (left figure) and maximal (right figure) transcutaneous carbon dioxide ( $\text{PtcCO}_2$ ) values observed at home and in the hospital in patients with neuromuscular disease (black circles) and with other disorders (open circles).

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3 For mean PtcCO<sub>2</sub>, regression lines are represented (plain for patients with  
4 neuromuscular disease (r=0.647, p=0.009) and dashed for patients with other  
5 disorders (r=0.564, p=0.037))  
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10 For maximal PtcCO<sub>2</sub>, regression lines are represented (plain for patients with  
11 neuromuscular disease (r=0.417, p=NS) and dashed for patients with other disorders  
12 (r=0.636, p=0.014).  
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17 Three patients having similar PtcCO<sub>2</sub> values, only 27 of the 29 spots are visible.  
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#### 20 21 22 **Figure 4**

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24 Comparison of percentage of nocturnal recording time spent with a PtcCO<sub>2</sub> > 50  
25 mmHg and ≤ 50 mmHg during the recordings performed in the hospital (black bars)  
26 and at home (grey bars).  
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Table 1: Characteristics of the patients.

	patients n=24
Age (years)	10 (4-19)
Male / Female	17 / 7
<i>Primary disease</i>	
neuromuscular disease	11
lung disease	3
upper airway obstruction	9
central hypoventilation	1
Duration of NPPV (months)	20 (3-62)
<i>Ventilatory mode</i>	
AC/VT	10
PS	5
Bilevel positive pressure	9
<i>Interface</i>	
industrial nasal mask	18
industrial face mask	3
custom made nasal mask	3

Data are given as median (range).

Abbreviations: NPPV: noninvasive positive pressure ventilation, AC/VT: assist control / volume targeted ventilation, PS: pressure support ventilation.

Table 2: Results of the recordings performed in the hospital and at home in the patients with neuromuscular disease and those with other disorders.

	Recordings in patients with neuromuscular disease n=15		p	Recordings in patients with other disorders n=14		p
	Hospital recordings	Home recordings		Hospital recordings	Home recordings	
Median value of the individual mean SpO <sub>2</sub> (%)	98 (94-99)	98 (97-100)	0.49	96 (93-99)	98 (95-99)	0.06
Median value of the individual minimal SpO <sub>2</sub> (%)	91 (82-97)	94 (75-97)	0.65	91 (80-93)	89 (87-93)	0.72
Median value of the individual mean PtcCO <sub>2</sub> (mmHg)	40 (32-51)	40 (32-51)	0.65	45 (37-53)	43 (33-55)	0.65
Median value of the individual maximal PtcCO <sub>2</sub> (mmHg)	48 (37-62)	45 (37-56)	0.07	49 (41-60)	47 (41-56)	0.07

Data are expressed as median (range).

SpO<sub>2</sub>: pulse oximetry, PtcCO<sub>2</sub>: transcutaneous carbon dioxide.

Figure 1

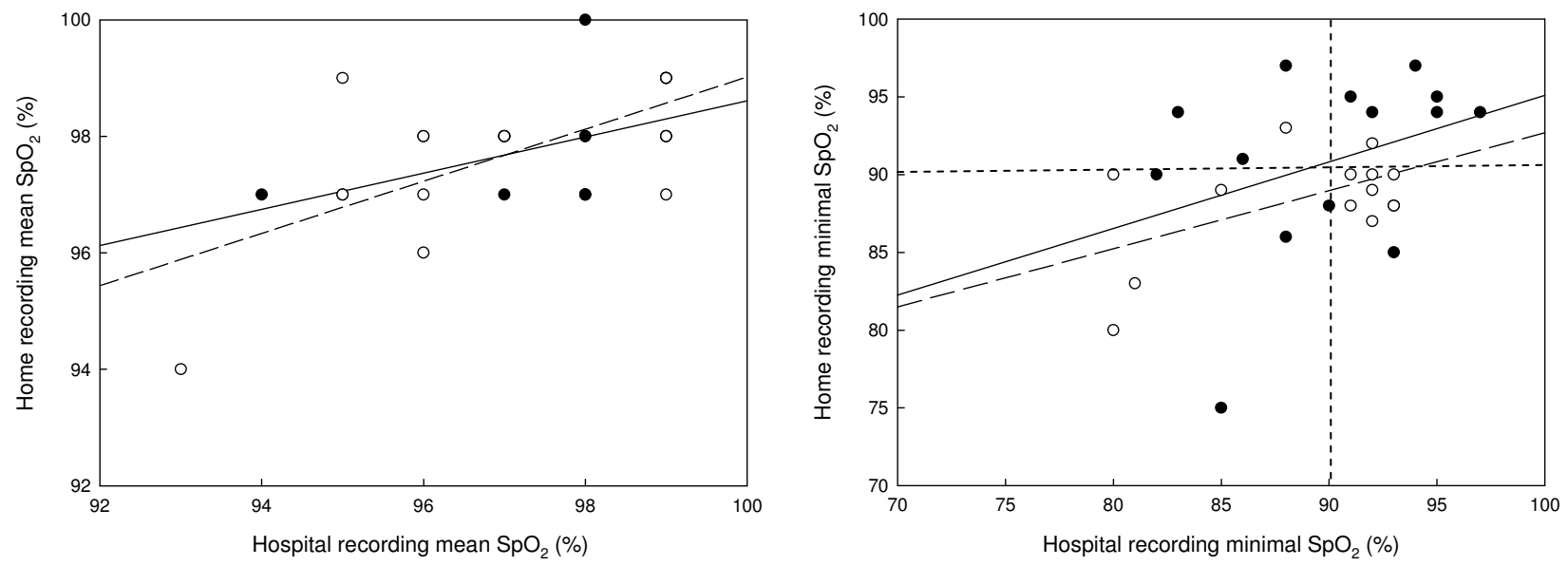
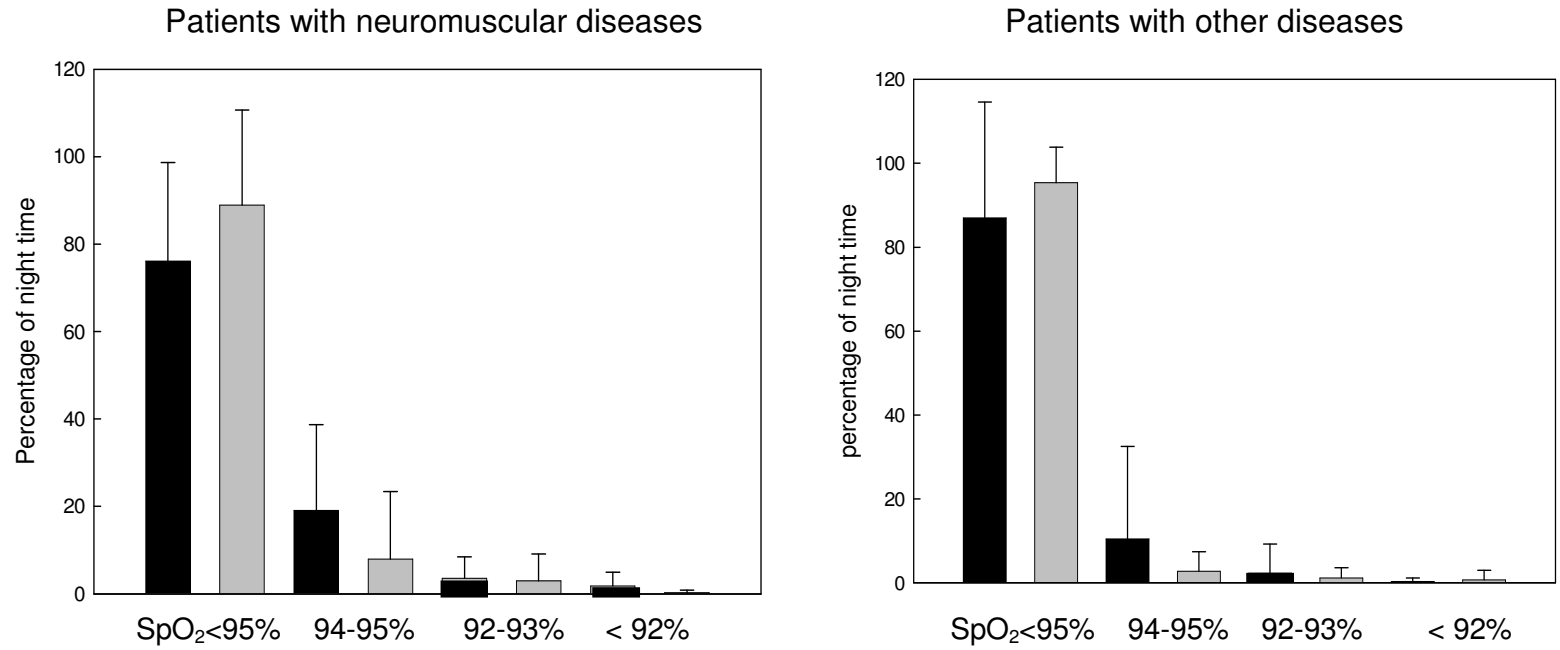


Figure 2



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Figure 3

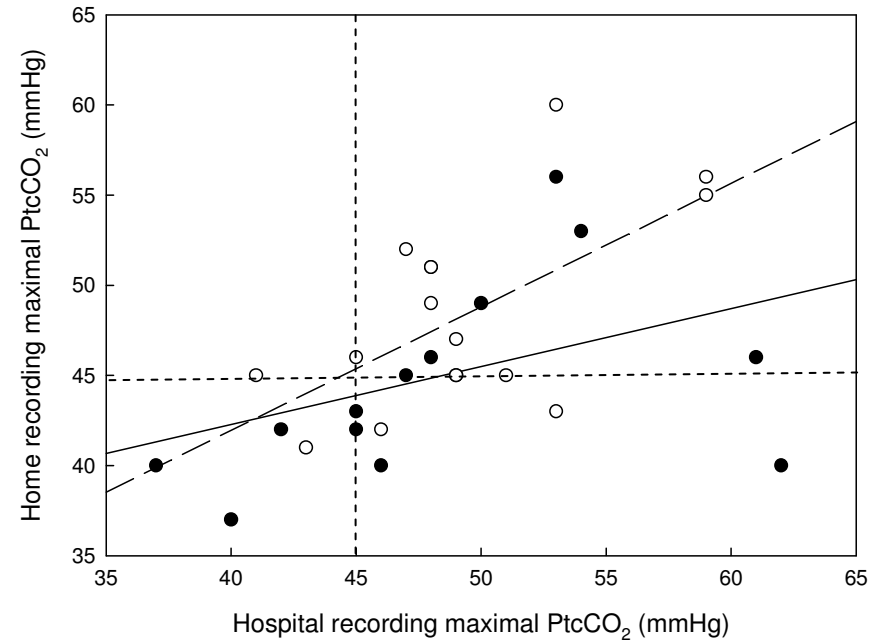
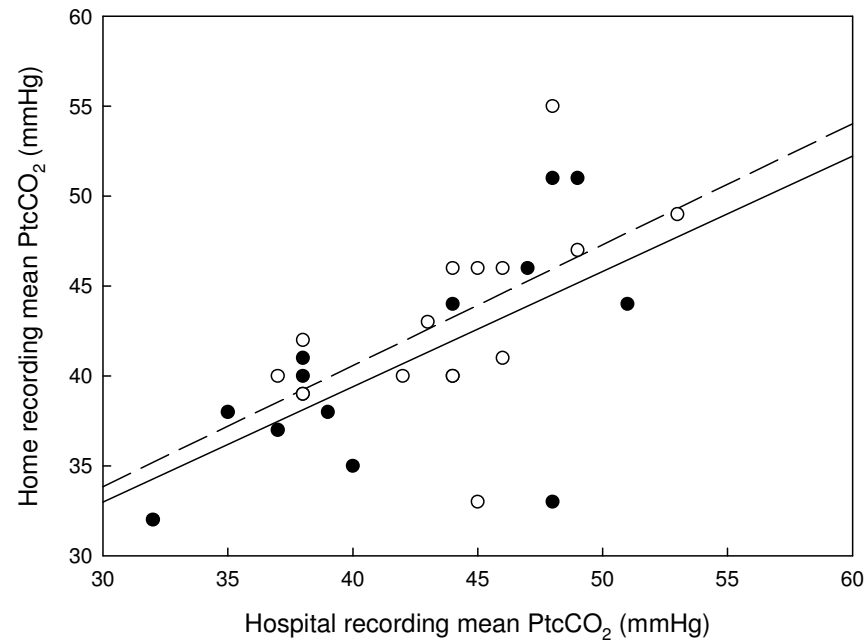


Figure 4

