# Clinical evidence on ambulatory oxygen systems

INVACARE

*Yes, you can.*

Invacare® | **Platinum™ Mobile**

## Clinical evaluation of the Invacare Portable Oxygen Concentrator

The ***Platinum Mobile*** concentrator was built to be the best oxygen partner for more active chronic respiratory insufficiency patients, but also to help minimize the risk factors associated with interstitial lung diseases, including prior or concomitant oxygen therapy.

The ***Platinum Mobile*** aims to provide a 'breath of new life' through this high quality medical device and, for professionals, the ability to confidently provide a device which has been rigorously tested, is highly robust and easy to maintain.

| Setting | P1 | P2 | P3 | P4 | P5 |
|---|---|---|---|---|---|
| Average pulse volume at 20 BPM | 11 ml | 22 ml | 33 ml | 44 ml | 50 ml |
| Average pulse volume at 30 BPM | 7.3 ml | 14.7 ml | 22 ml | 29.3 ml | 33.3 ml |
| Minute volume (ml) | 220 | 440 | 660 | 880 | 1000 |
| Battery duration (hours)* | 5h05min | 3h30min | 2h20min | 1h45min | 1h45min |
| Battery duration (hours)* Two battery pack | 10h10min | 7h | 4h40min | 3h30min | 3h30min |

*Times are approximate

## Technical data

For more comprehensive pre-sales information about this product, including the product's user manual, please refer to your local Invacare website.

| Total height | Total width | Total depth | Weight | AC Charger | DC Charger | FAA | Pulse dose delivery |
|---|---|---|---|---|---|---|---|
| 239 mm | 188 mm | 94 mm | 2.22 kg concentrator<br>0.45 kg supplemental battery<br>0.34 kg carry bag | 100-240 VAC<br>50-60 Hz | 11-16 VDC | FAA compliant | Settings 1-5 up to 1000 ml per minute |

| O2 purity | Environmental tolerance | Power consumption | Sound level | Battery charging time | Trigger sensitivity | Nasal cannula length |
|---|---|---|---|---|---|---|
| 87% - 95.6% | Concentrator IP22<br>env.t° from 5°C to 40°C | 24W<br>at setting 2 | ≤ 40 db(A)<br>at setting 2 | 2h20min with 1 battery<br>4h40min with 2 batteries | 0.18 cm H2O average with ≤0,18 cm H2O at Setting 2 at 20 bpm | From 1200 mm to 2100 mm for best efficiency |

## Source data

**Authors:**
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**Source:**
Antadir Federation, July 2017

**Title:**
Clinical evaluation of the medical device

# GENERAL CONCLUSIONS OF THIS CLINICAL EVALUATION OF THE PLATINUM MOBILE CONCENTRATOR

The results of this clinical evaluation of patients with chronic respiratory insufficiency show that in most cases the clinical performance of the Platinum Mobile concentrator device, which features a pulse mode, is comparable to that of a liquid oxygen therapy device (C500) used in continuous mode, in terms of exercise tolerance, symptomatology and correction of resting oxygen saturation and stress.

However, it is important to note that the clinical efficacy of the Platinum Mobile concentrator varies from one patient to another, especially on parameters of oxygen saturation.

Each prescription must be individualized and checked by a standardized titration test (oximetry during a 6-minute walking test). Learning how to utilize oxygenation in the pulse mode requires a period of adaptation and instruction.

Noise remains the main disadvantage of this device. Finally, the 'concentrator' technology is assessed highly, because it enables liberation from the constraint of oxygen filling and effects a true increase in autonomy in daily life.

# 1. RESEARCH DESIGN

### 1.2. OPERATIONAL ISSUES

Six centers with expertise in respiratory pathology participated in the multi-center development of this study [Table 1]. In order to avoid cultural and geographical biases, we have developed this study with centers of sectors (public or liberal) and regions (different climatic conditions) on French territory. These centers carried out the clinical evaluations in accordance with the standardized procedure proposed by the Medical-Technical and Social Commission (CMTS) of the Fédération ANTADIR. To limit the 'evaluator-dependent' biases, one principle investigator was assigned on each site to carry out the evaluations as a whole. The anonymous information was collected in an individualized, follow-up log book then digitally captured and analyzed independently by qualified members of ANTADIR's CMTS.

| Cities | Locations | Referent investigators |
|---|---|---|
| DIEULEFIT | Centre de Réadaptation Cardio-Respiratoire | Dr F. HERENGT / Dr D. VEALE |
| LA ROCHELLE | Centre Hospitalier | Dr DORE / Dr LEMERRE / Dr LEVRAT |
| LIMOGES | Hôpital Dupuytren | Dr. F. FAVARD |
| NANTES | Hôpital Nord Laennec | Dr. A. CHAMBELLAN |
| PARIS | Hôpital Pitié Salpêtrière | Dr L. LAYACHI |
| ROUEN | CHU Rouen | Pr. JF. MUIR |

Table 1: Referent investigators' centers

# 2. RESEARCH METHODOLOGY

This study is prospective, randomized, open, comparative and multi-center. Each patient is self-reporting.

### 2.1. CRITERIA FOR INCLUSION/ EXCLUSION

Patients included (men and women) had respiratory disease at the stage of chronic respiratory insufficiency and had oxygen therapy at rest and/or ambulatory oxygen therapy. According to the investigators, each patient was stable and not suffering from a cold at the time of the evaluations. In order to avoid familiarization bias, we ensured that the included patients had already completed a 6-minute walking test and were, in the opinion of the investigator, able to achieve the best possible outcome for this protocol.

Prior to inclusion, each patient clearly understood the conditions and research procedure, and then signed the consent form with the agreement of the referring pulmonologist. We excluded those patients presenting a history of angina, recent heart attack (<1 month), progressive coronary pathology and any other instance contraindicating the implementation of a stress test. We also excluded those patients presenting cognitive or motor problems that significantly limited the comprehension or the performance of evaluations.

### 2.2. RESEARCH PROTOCOL DESCRIPTION

We collected the usual anthropometric and medical variables and data on the history of patient oxygen therapy (age and daily prescription). Resting dyspnea was measured by the French version of the Medical Research Council (MRC) scale, which is the Sadoul scale [1] and the respiratory function evaluated by measuring the flow / volume curves using a spirometer (used routinely in the investigating center). We selected the forced vital capacity (FVC) values, the maximum expiratory volume in 1 second (FEV 1) and then calculated the Tiffeneau ratio, in accordance with the current European normal values [2].

Each patient underwent two 6-minute walking tests (6MWT) following a random draw: one test with continuous flow oxygen (C500) constituting the ‘control’ group and the other with the Platinum Mobile concentrator in Pulsed mode, constituting the ‘experimental’ group. Before each 6MWT, the patients were seated for 30 minutes of rest with one or another oxygen therapy device. Knowing that arterial oxygenation continues to increase within the first 15 to 30 minutes of oxygen therapy, this 30-minute time allowed us to ensure the titration of the devices [Figure 1]. For the 6MWT with the medical Platinum Mobile device, the chosen adjustment position was gradually adjusted to ensure an oxygen saturation ≥ 92% at rest before the walking test. For the 6MWT with the C500 device, the oxygen flows were in accordance with the medical prescription of patient perambulation and the tests started with a saturation at least equal to 92%.

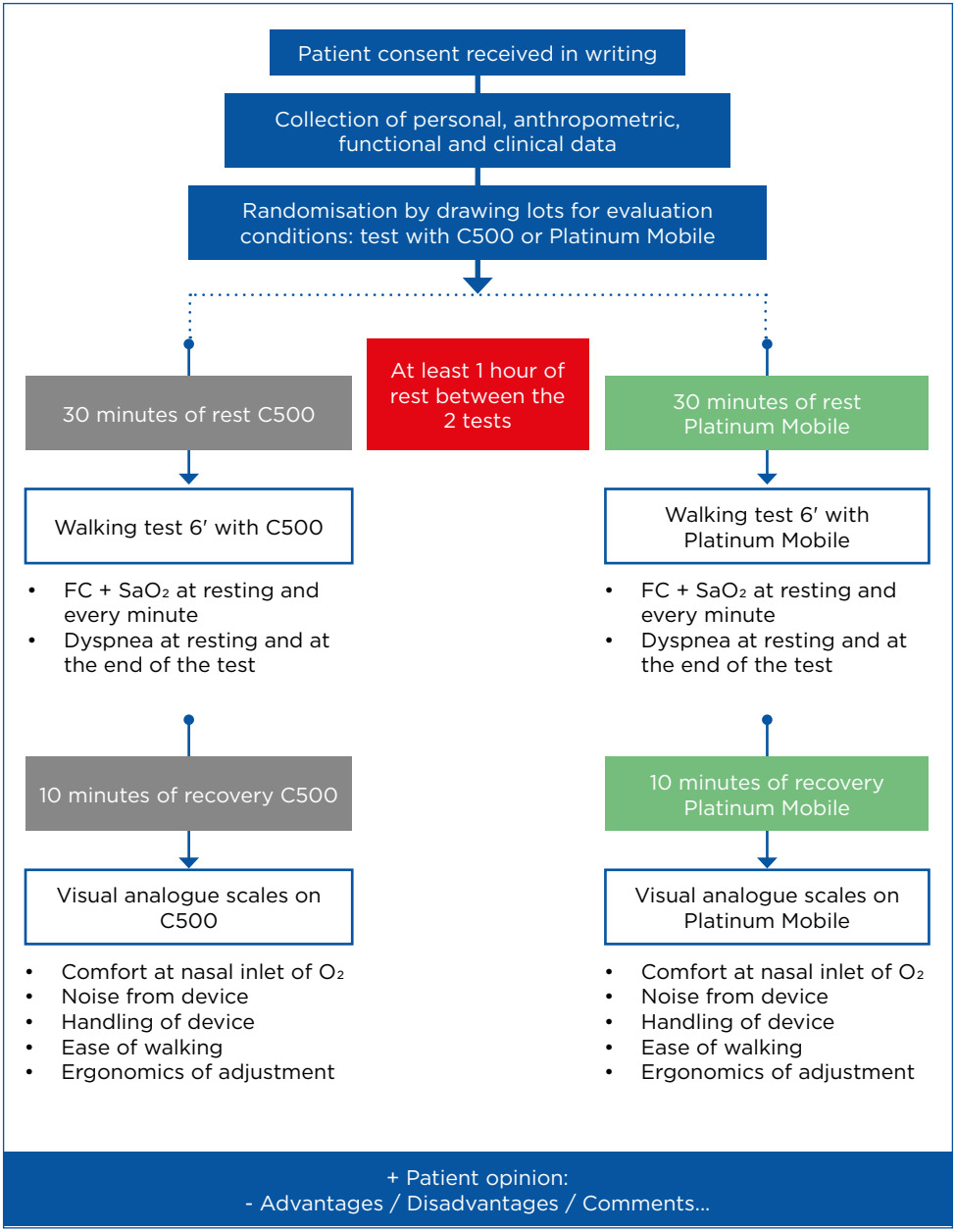


**Figure 1**
Walking test 6'->6'wlaking test FC->HR (Heart rate)

6MWT were performed according to a standardized procedure, in accordance with the international recommendations in force [3] and with one hour of recovery between the tests. Starting the test with the C500 or the Platinum Mobile concentrator was determined by drawing lots. In each case, the devices were either pulled on a two-wheel carrier or carried by the patient (the C500 device was previously filled with O2 so as to standardize the weight for the entire study population). During each 6MWT, dyspnea at rest and exertion-induced dyspnea was evaluated using a standardized, visual analogue scale (VAS) [4] and heart rate and oxygen saturation values (SaO2) were recorded every minute.

At the end of each test, the patients completed standardized visual analogue scales [4] relative to the perception of O2 in the nose, the device's noise and its weight [Figure 1]. The results are expressed as a percentage for the qualitative variables and as a mean ± standard deviation for the quantitative variables. Statistical differences were considered significant at the 5% threshold ($p<0.05$).

## 3. CHARACTERISTICS OF THE POPULATION STUDY

Thirty patients were enrolled over the period from January 2017 to June 2017. In total, of the 30 patients, 15 men and 15 women aged 64.9 years ± 8.9, with a body mass index of 23.6 kg.m$^2$ ± 7.3 were included [Table 2]. Overall, 11 patients with severe COPD, 17 patients with very severe COPD and 2 patients with bronchiectasis. The average forced expiratory volume in one second was 32.71% ± 10.48 theoretical values [5] and PaO2 in ambient air of 61.67 mm Hg ± 10.29 (n = 25).
Of the total population, 22 patients utilized oxygen therapy at rest and while ambulatory, 6 patients used oxygen only when ambulator, and 2 patients used oxygen only at rest. Six patients had been receiving oxygen therapy for less than a year; 17 for 1 to 5 years; and 7 patients for more than 5 years. For all patients, the mean flow rate prescribed for perambulation was ≤ 3l/min, as recommended by the manufacturer (2.27 l ± 0.92).

Levels of dyspnea (Sadoul scale) were variable, ranging from level 1 (dyspnea at average exertion) to level 5 (dyspnea at least exertion), with a mean value at 3.60 ± 1.28.

| ANTHROPOMETRIC DATA | |
|---|---|
| Ratio men/women | 15/15 |
| Age (years) | 64.9 ± 8.9 |
| Body mass index (kg. m$^2$) | 23.6 ± 7.3 |
| **Dominant pathology (n)** | |
| Stage III COPD | 11 |
| Stage IV COPD | 17 |
| Bronchial dilations | 2 |
| **Oxygen therapy prescription** | |
| Oxygen therapy at rest and whilst walking (n) | 22 |
| Oxygen therapy exclusively whilst walking (n) | 6 |
| Oxygen therapy exclusively at rest (n) | 2 |
| Average flows at ambulation (l/min) | 2.27 ± 0.92 |

Table 2: Characteristics of the Population Studied

# 4. CLINICAL EVALUATION RESULTS

## 4.1. CLINICAL EFFICACY OF THE PLATINUM MOBILE CONCENTRATOR

### ACTIVATING THE VALVE

At rest, all patients were able to trigger the Platinum Mobile concentrator valve. The valve trigger to respiratory cycle ratio was 0.97 ± 0.08. Six patients had non-direct oral respiration. There was no association between this mode of respiration and the valve's triggering capacity.

### DISTANCE TRAVELLED IN THE 6-MINUTE WALKING TEST (6MWT)

Of the total 30 patients, 7 patients were excluded from the statistical analysis due to methodological bias of the protocol (SaO2 <92% at start of walking test and modification of oxygen concentrator settings during the test).

Of the 23 patients, the distance travelled during the 6MWT was comparable with the Platinum Mobile concentrator in pulsed mode (344 m ± 111) and the C500 continuous liquid oxygen device (350 m ± 114) [Figure 2]. There is no significant difference between distance travelled with either the C500 or the Platinum Mobile concentrator with both devices, p = 0.869, $R^2$ = 0.894 [Figure 3].

However, 9 patients out of 23 covered a longer distance during the 6MWT with the Platinum Mobile concentrator. These benefits were on average 8.79% ± 10.15, with 2 patients showing an improvement >10%, i.e. above the threshold of clinically perceived benefits. Twelve patients performed worse with the Platinum Mobile concentrator compared to the C500. On average, the decrease in distance during the 6MWT for these patients was -7.67% ± 8.77, including 3 patients with a decrease of >10%.

These 3 patients performed their 6MWT with the Platinum Mobile concentrator at setting position 3 and 4. Nevertheless, our analysis shows that the performance during the 6MWT is not significantly related to the adjustment position or the oxygen flow used during the tests, nor does it appear to be related to the pathology or its severity, nor to the body mass index or to a preferentially oral respiratory mode.

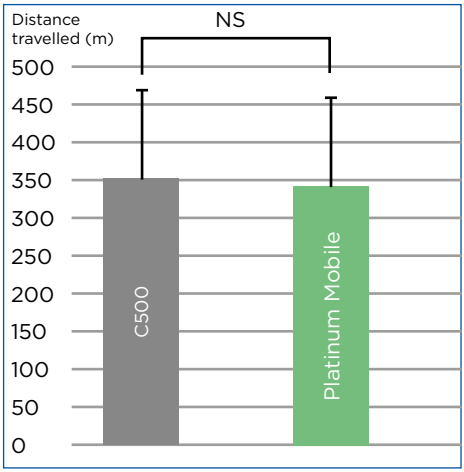


**Figure 2**
Average distance (± SD) in the 6-minute walking test (6MWT) with the C500 device and Platinum Mobile on the population of 23 patients. NS: Non-significant difference

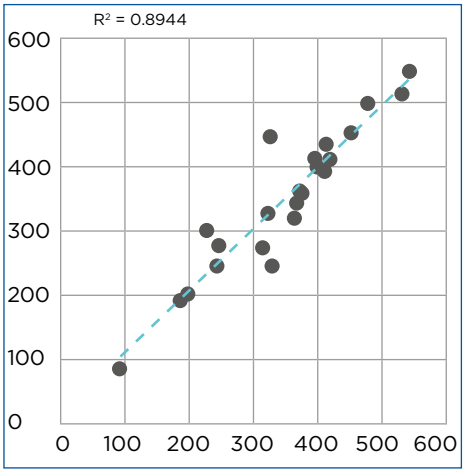


**Figure 3**
Correlation between the distance travelled in the 6-minute walking test (6MWT) with the C500 device and with Platinum Mobile on the population of 23 patients. $R^2$ Correlation coefficient

## DYSPNEA AT REST AND EXERTION-INDUCED DYSPNEA

Average dyspnea (VAS) was analyzed in 23 patients. Average dyspnea at rest was similar in both conditions: 1.30/10 ± 1.72 with the Platinum Mobile concentrator and 1.26 10 ± 1.66 with the C500. The use of either device did not significantly alter the symptomatology to exercise: 6MWT induced dyspnea was 5.61 / 10 ± 3.14 with the Platinum Mobile concentrator and 5.89/10 ± 2.96 with C500 [Figure 4].

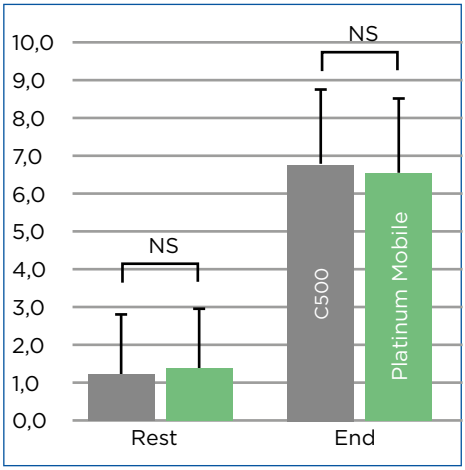


**Figure 4**
Average dyspnea (± SD) measured by VAS at rest and after 6-minute walking test (6MWT) with the C500 device and Platinum Mobile on the population of 23 patients. NS: Non-significant difference

## OXYGEN SATURATION AT REST AND AFTER 6MWT:

Of the total of 30 patients, 7 patients were excluded from the statistical analysis due to methodological bias of the protocol (SaO2 <92% at start of walking test and modification of oxygen concentrator settings during the test).
Of the 23 patients, the SaO2 at rest was 95.1 % ± 2.0 with the Platinum Mobile concentrator and 94.8 % ± 2.1 with the C500. The variability of this parameter on exercise is such that we chose to distinguish 4 groups of patients:
The 'non desaturators': of the 23 patients, 9 showed no desaturation during the 6MWT with either the Platinum Mobile concentrator or the C500. For this 'subgroup', the oxygen saturation at rest was 96.1% ± 2.3 with the Platinum Mobile concentrator and 95.1% ± 2.3 with the C500. The oxygen saturation at the end of the 6-minute walking test was 91.2% ± 2.9 with the Platinum Mobile concentrator and 93.3% ± 3.1 with the C500 [Figure 5].

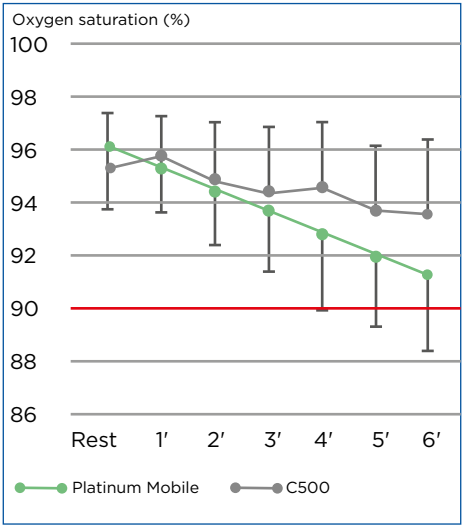


**Figure 5**
Evolution of oxygen saturation in the 'non desaturator' subgroup (n = 9) in the two standardized 6-minute walking tests.

The desaturators: of the 23 patients, 9 showed desaturation during the 6MWT, with the Platinum Mobile concentrator and the C500. Desaturation was defined as SaO2 <90% for at least 3 consecutive minutes during 6MWT. For this 'subgroup', the oxygen saturation at rest was 94.3% ± 1.8 with the Platinum Mobile concentrator and 95.2% ± 2.2 with the C500. The oxygen saturation following the 6MWT was 81.0 % ± 4.5 with the Platinum Mobile concentrator and 82.8 % ± 5.3 with the C500. The amplitude of the desaturation was on average 14.0% ± 4.0 with the Platinum Mobile concentrator and 12.6% ± 4.4 with the C500. The lowest level of oxygen saturation reached on average during 6MWT was 80.3% ± 4.4 with the Platinum Mobile concentrator and 82.7% ± 4.8 with the C500. Desaturation and amplitude are similar in both groups [Figure 6]. The number of stops during 6MWT did not differ significantly in the two conditions (0.35 ± 0.78 with the Platinum Mobile concentrator and 0.22 ± 0.67 with the C500 p = 0.54).

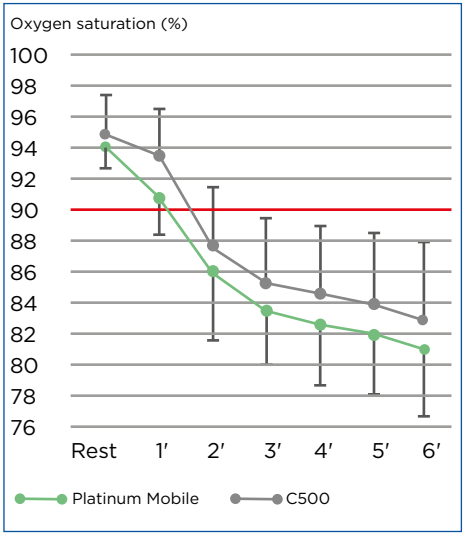


**Figure 6**
Evolution of oxygen saturation in the subgroup 'Desaturators' (n = 9) in the two standardized 6-minute walking tests

**The 'Conditional Desaturators 1':** This 'subgroup' comprises 3 patients who desaturated during the 6MWT with the Platinum Mobile concentrator, but did not desaturate during the 6MWT with the C500. It should be noted that the 6MWT with the Platinum Mobile concentrator in position 4 were performed for these 3 patients [Appendix 1]. The amplitude of the desaturation was on average 9.3% ± 2.3 with the Platinum Mobile and 4.0% ± 1.0 with the C500 concentrator. The lowest level of oxygen saturation reached on average during the 6MWT was 85.3% ± 2.1 with the Platinum Mobile concentrator and 89.7 % ± 1.2 with the C500 [Figure 7].

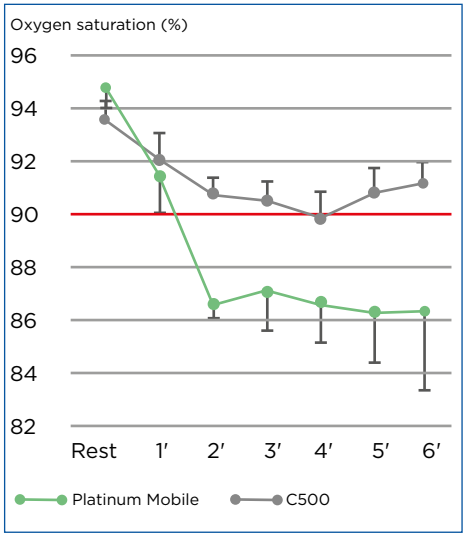


**Figure 7**
Evolution of oxygen saturation in the 'Conditional desaturator 1' subgroup (n = 3) in the two standardized 6-minute walking tests. Patients desaturate with the Platinum Mobile and not with the C500 during the 6MWT.

The 'Conditional Desaturators 2': This 'subgroup' comprises 2 patients who did not desaturate during the 6MWT with the Platinum Mobile concentrator whereas they did desaturate during the 6MWT with the C500 [Appendix 2]. The amplitude of the desaturation was on average 6.5% ± 0.7 with the Platinum Mobile concentrator and 6.5% ± 2.1 with the C500. The lowest mean oxygen saturation during 6MWT was 88.0% ± 1.4 with the Platinum Mobile concentrator and 86.5% ± 0.7 with the C500 [Figure 8].

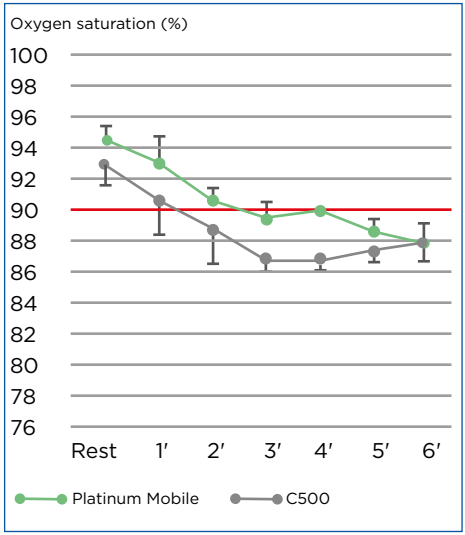


**Figure 8**
Evolution of oxygen saturation in the 'conditional desaturator 2' subgroup (n = 2) in the two standardized 6-minute walking tests. Patients desaturate with the C500 and not with the Platinum Mobile concentrator during the 6MWT

## 4.2. PATIENT ASSESSMENT OF THE PLATINUM MOBILE CONCENTRATOR

Patients were asked to complete a visual analogue scale (VAS) for 5 points at the end of each test [Appendix 3]. For each of the following three items were analyzed: the inconvenience caused by the arrival of oxygen via the nasal bezel, the irritation caused by the noise of the concentrator and the discomfort caused by the weight of the device were analyzed. The lower the score on the scale, the better the patient's assessment of the item.

### THE NASAL OXYGEN INFLOW

Of the 30 patients, the discomfort caused by the inflow of oxygen in the nose was on average greater with the Platinum Mobile concentrator 2.5/10 ± 2.7 as opposed to 0.5/10 ± 1.4 with the C500; significant difference, p = 0.001). Individually, 9 patients found discomfort with the Platinum Mobile concentrator greater (difference in score ≥2) than with the C500 (the patient is hampered by the oxygen inflow in the pulse mode, a familiarization period seems necessary to comprehend this mode of oxygenation, during major exertion, and especially at the end of a walking test, nasal breathing is difficult). For the other patients (70% of the cases), the nasal discomfort at the arrival of O2 was similar with the two devices, i.e. a difference in score of less than 2 [Figure 9].

**THE DEVICE NOISE**

In general, patients judged the noise of the Platinum Mobile concentrator to be significantly more bothersome than that of the C500 (5.1 ± 3.0 vs 0.3 ± 0.4; p <0.01). In 80% of the cases, the noise of the Platinum Mobile concentrator was considered more troublesome than that of the C500 (difference ≥2 out of 10 on the VAS). In 20 % of the cases, the noise of the Platinum Mobile concentrator was considered identical to that of the C500 (difference <2 out of 10 on the VAS) [Figure 9].

**THE DEVICE WEIGHT**

Overall, patients felt that the discomfort caused by the weight of the device was significant between the Platinum Mobile concentrator and the C500 (1.6/10 ± 1.7 vs 3.3/10 ± 3.2; p = 0.011). However, in 36.7% of the cases, the discomfort caused by the weight of the Platinum Mobile concentrator was judged to be less than that caused by the C500 (difference ≥2 out of 10 on the VAS). And in 53.3% of the cases, the discomfort was judged identical between the two devices (difference <2 out of 10 on the VAS) [Figure 9].

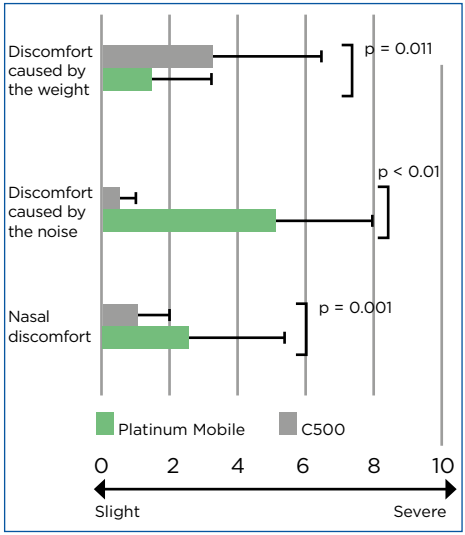


**Figure 9**
Subjective assessments of C500 and Platinum Mobile devices by patients using visual analogue scales from 0 to 10 (n = 30) (mean value ± SD)

## 5. PATIENTS' GENERAL COMMENTS ABOUT THE PLATINUM MOBILE CONCENTRATOR

When we asked about the main advantages and disadvantages of the Platinum Mobile concentrator device, patients emphasized the weight of the device, which they considered lightweight and compact. As part of this evaluation, patients wore the Platinum on a shoulder strap. Some patients appreciated that Platinum Mobile can be transported by backpack. Indeed, the use of a backpack makes it possible to better distribute the weight to be carried over the whole body, limits joint discomfort (especially to the shoulders) and allows the patients to have both hands free for activities, such as gardening or biking during their rehabilitation. Some patients emphasized the ergonomic aspect of the Platinum Mobile concentrator. The device is small, easy to handle and discreet.

The main disadvantage of the Platinum Mobile device, as stated by the patients, was the problem of noise. Some people thought it could be an annoyance for company or in public places (e.g. cinema, restaurant, etc.). Nevertheless, it was also reported that the convenience factor overrides the noise.

The advantage of not having a tank of liquid oxygen at home and thus avoid needing to fill portable stations. This advantage frees the patients from the oxygen-filling constraint and grants them more autonomy. The technology of the concentrators facilitates access to oxygen and allows for greater freedom of movement (recharging on the grid or via cigarette lighter, etc.).

This would make it possible to envisage better mobility and frequent movements without the need for an additional source of oxygen. They associate this technological evolution with a gain of freedom and autonomy in their daily life. As for the use of the pulse mode, there is a variability of reactions to this item. Most patients adapt to the delivery of the oxygen bolus and learn nasal respiration without difficulty. However, some patients require a period of adaptation and training in the pulse mode. Predominantly nasal respiration is not always obvious.

Finally, the patients gave their opinions on the criteria that they consider important for an ambulatory device. The first criterion is the weight of the device with a plurality of 41% as the first choice. The need for a silent device (31% of second choices), its autonomy (28% of third choices) and its discretion (48% of the fourth choices) are important criteria in choosing an oxygen therapy device. Finally, patients felt that ease of handling (31% of the fifth choice) and being freed from filling bottles (31% of the sixth choices) seemed the least important.

## 7. BIBLIOGRAPHY


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# *Invacare®* | **HomeFill® II**

- Provides an unlimited, refillable ambulatory oxygen supply
- Continuous-flow up to 6 LPM and pulse-dose settings 1-5 meet a broad range of patients needs
- Lightweight cylinders: 1.6 kg (1 L) or 2.2kg (1.7 L)
- Small compact cylinders: D 11cm x H 30cm (1 L) or H 35.5cm (1.7 L)
- Oxygen concentration: 93% +/- 3%
- Cylinders fill time: 1hrs (1 L) or 2hrs (1.7 L)
- Easy cylinder connection with the HomeFill II compressor coupler
- Electrical consumption: 175 W max.
- Patients breathe from a continuous flow oxygen concentrator at night
- Compatible with Perfect$O_2$, Perfect$O_2$ V and Platinum® 9

| HomeFill cylinder (1L, 1.86kg) with conserving device autonomy in hours @20 bpm | | | | | |
|---|---|---|---|---|---|
| Conserver setting | 1 | 2 | 3 | 4 | 5 |
| Average bolus volume (ml) | 13 ml | 21 ml | 28 ml | 35 ml | 43 ml |
| Minute volume flow (ml/ min) | 260 ml | 420 ml | 560 ml | 700 ml | 860 ml |
| Autonomy in pulse-dose (hr) | 9h50 | 5h40 | 4h15 | 3h30 | 3h |
| Autonomy in continuous-flow at 2 LPM (hr) | | 1h20 | | | |

| HomeFill cylinder (1.7L, 2.3kg) with conserving device autonomy (hr) @20 bpm | | | | | |
|---|---|---|---|---|---|
| Pulse-dose setting | 1 | 2 | 3 | 4 | 5 |
| Average bolus volume (ml) | 13 ml | 21 ml | 28 ml | 35 ml | 43 ml |
| Minute volume flow (ml/ min) | 260 ml | 420 ml | 560 ml | 700 ml | 860 ml |
| Autonomy in pulse-dose (hr) | 15h | 8h40 | 6h30 | 5h20 | 4h40 |
| Autonomy in continuous-flow at 2 LPM (hr) | | 2h | | | |

| HomeFill cylinder (1.7L, 2.3kg) with continuous flow regulator (hr) | | | | | | |
|---|---|---|---|---|---|---|
| Continuous-flow (LPM) | 0,25 | 0,5 | 0,75 | 1 | 1,5 | 2 |
| Autonomy (hr) | 16h | 8h | 5h20 | 4h | 2h40 | 2h |
| Continuous-flow (LPM) | 2,5 | 3 | 4 | 5 | 6 | |
| Autonomy (hr) | 1h30 | 1h20 | 1h | 50 mn | 40mn | |

## Source data

**Authors:**
Cuvelier A, Muir JF, Chakroun N, et al.

**Source:**
Chest 2002 vol 122(2) :451-456

**Title:**
Refillable oxygen cylinders may be an alternative for ambulatory oxygen therapy in COPD

## STUDY AIM AND DESIGN

• This is a prospective randomised study with a cross-over design **aimed to compare the efficacy of continuous-flow oxygen delivered with HomeFill® refilled oxygen cylinders ($O_2$-HF) and conventional oxygen cylinders ($O_2$-C)**
• Ten (10) patients with stable oxygen-dependent COPD were included and **performed three (3) successive 6-min walking test (6MWT)**. All patients were previously treated with continuous-flow long-term oxygen therapy
• Each patient performed a baseline reference 6MWT carrying a new $O_2$-C with nasal prongs, whilst breathing room air
• **The walking tests were performed with $O_2$-HF or $O_2$-C in randomised order** and both 6MWT under oxygen were performed with a 2 L/min continuous-flow
• Transcutaneous $SaO_2$ and cardiac frequency were recorded and dyspnea was **measured at rest after exercise with a Borg scale**
• Both $O_2$-HF and $O_2$-C oxygen purity were measured regularly with an oxygen sensor

## KEY FINDINGS

• **Mean $SaO_2$ values with $O_2$-C and $O_2$-HF were very similar throughout the walking test**
• Mean cardiac frequencies were very similar under each condition. **No significant individual cardiac intolerance was observed**
• **Mean dyspnea score, measured with the Borg scale, did not significantly change** after the walking test and were not significantly different with either $O_2$-C or $O_2$-HF
• **Clinical improvement was significant with both $O_2$-HF or $O_2$-C, in a real-life situation like an exercise test**
• The study concluded that **clinically efficacy of continuous-flow oxygen from refilled oxygen cylinders ($O_2$-HF) is equivalent to continuous-flow oxygen from conventional cylinders ($O_2$-C)**

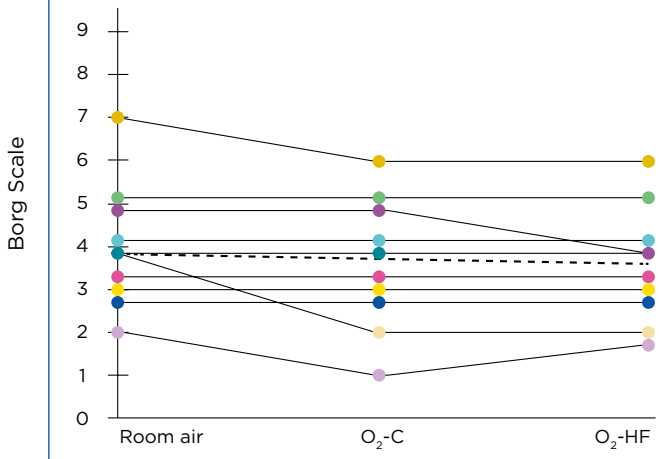
## KEY QUOTES

• "**$SaO_2$ improvements are equivalent with both oxygen supplies** and demonstrate a similar performance between $O_2$-HF and $O_2$-C"
• "These results were **obtained in spite of a lower filling gas pressure** and a slightly lower oxygen purity in $O_2$-HF (140 bars and 94.24 +/- 2.56%) as compared to $O_2$-C (200 bars and 98.85 +/- 4.89%)."
• "**The actual average FIO2 received by the patients does not differ significantly** when considering the entraining room air via the Venturi Effect."
• "We suggest that performances (mean distances, dyspnea score) achieved through the walking tests are similar with both oxygen devices."
• "**Substitution of gaseous oxygen by liquid oxygen therapy for all hypoxemic COPD patients is not medically justified** and is not largely available in most countries for economic reasons."
• "$O_2$-HFs may be a good compromise at home since **ambulatory patients will be able to manage their physical autonomy without the constraints of oxygen home delivery** and with overall decreasing costs."

## KEY ILLUSTRATIONS

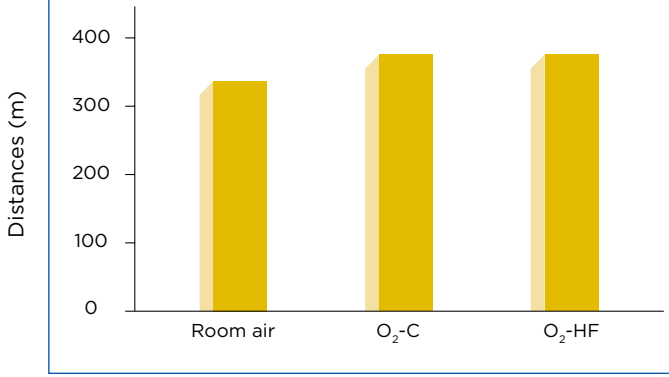
Mean dyspnea scores after walking test in room air were not significantly different from $O_2$-C and $O_2$-HF. Scores of patient 1 to 10 shown in Figure 1.

**Figure 1**




Mean walking distance significantly increased with both $O_2$-C and $O_2$-HF, and no statistical difference was found between the two groups.

**Figure 2**



## Source data

**Authors:**
Lewarski, J, Mikus, G, Andrews, G, Chatburn, R.

**Source :**
Respir Care 2003 Vol. 48(11); 1115

**Title:**
A clinical comparison of portable oxygen systems: Continuous flow compressed gas vs. oxygen concentrator gas delivered with an oxygen conserving device

## STUDY AIM AND DESIGN

• This is a prospective randomised study with a cross-over design **aimed to compare clinical efficacy of conventional gas continuous-flow oxygen cylinders ($O_2$-C) and HomeFill® refilled pulsed-flow oxygen cylinders ($O_2$-HF)**
• Nine (9) patients with stable, uncomplicated oxygen-dependent COPD were randomly assigned to continuous-flow oxygen with $O_2$-C (99.6% USP*) or pulsed-flow $O_2$-HF (93% USP) delivery system
• **All patients were existing home oxygen users with an $O_2$ prescription of 3LPM or less and had the ability to carry portable devices**. Oxygen litre flow (lpm) and settings were consistent with their current prescription
• **A standard 6-minute walking test (6MWT) was used to assess exercise capacity and tolerance**
• Distance walked (m), heart rate (rpm), pulse oxymetry arterial oxygen saturation ($SpO_2$) and dyspnea (Borg scale) were **recorded before and after the 6MWT to evaluate the clinical response to each system**

## KEY FINDINGS

• **The study concluded that clinically efficacy of pulse-dose oxygen from refilled oxygen cylinders ($O_2$-HF) is equivalent to continuous-flow oxygen from conventional cylinders ($O_2$-C)**
• The modest difference in the delivered oxygen purity between $O_2$-HF (93%) and $O_2$-C (99.6%) does not affect clinical outcomes
• **There was no effect of device on either $SpO_2$ or heart rate and there was no difference in the Borg score between the two groups**

## KEY QUOTES

• "These results suggest that the type of oxygen delivery device used and the modest difference in the delivered oxygen percentage **does not affect clinical outcomes**"
• "Compressed oxygen derived from a concentrator at 93% $O_2$ and delivered in conjunction with a pneumatic $O_2$-conserving device **provides the same clinical benefit as the standard 99.6% $O_2$ continuous flow device**"
• "Practical benefits of a transfilling oxygen concentrator system include **patient freedom to refill their compressed gas cylinders at their own schedule, leading to improved portability**"
• "The use of refilled oxygen cylinders ($O_2$-HF) in stable ambulatory users appears to be **a safe and reliable alternative to traditional compressed oxygen gas ($O_2$-C)**"

*United States Pharmacopeial Convention (USP)

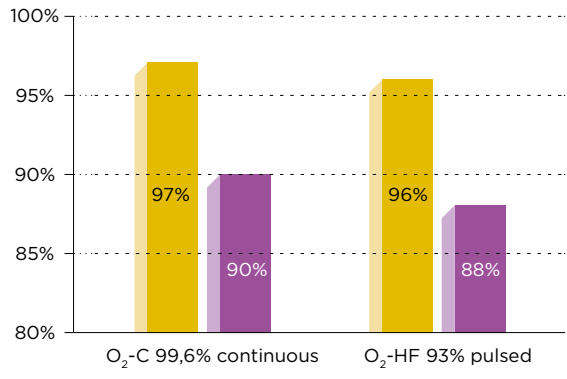
# KEY ILLUSTRATIONS

**$SpO_2$**

Before 6MWT

After 6MWT

**Figure 1**

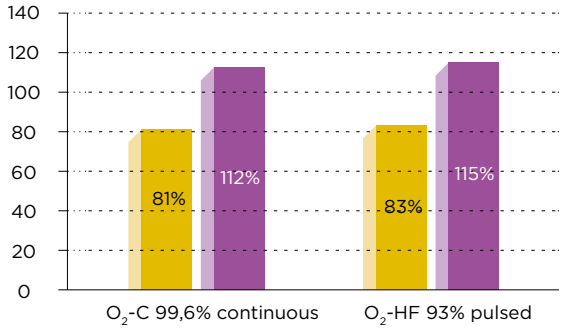



**Heart rate**

Before 6MWT

After 6MWT

**Figure 2**




**Borg scale**

Before 6MWT

After 6MWT

**Figure 3**

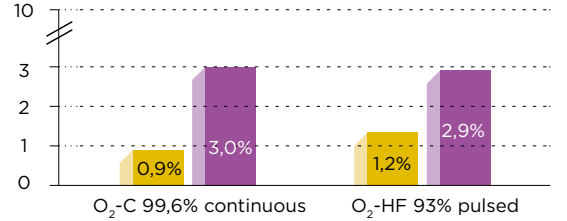



**Figure 1, 2 and 3**
The modest difference in the delivered oxygen purity does not affect clinical outcomes

## Source data

**Authors:**
Turnbull J, L McDonnell, AC Davidson

**Source:**
Thorax 2012;67(Suppl 2):A83

**Title:**
Patient activity levels and oxygen device preference: an RCT comparing HomeFill® refillable cylinders with usual ambulatory devices

## STUDY AIM AND DESIGN

• This prospective randomized study has a cross-over design **aimed to assess patients activity and preference using HomeFill® versus usual ambulatory oxygen devices in a mixed population of patients with exercise hypoxaemia and/or Long-term Oxygen Therapy (LTOT)**
• **Twenty-nine (29) patients with stable oxygen-dependent COPD were included and randomised in a cross-over design**. In Cohort A, patients received 6 weeks ambulatory oxygen HomeFill® and then 6 week of their usual ambulatory oxygen device, and vice versa in Cohort B
• All patients were previously treated with ambulatory long-term oxygen therapy and **ambulatory oxygen was optimized at baseline**
• **Weekly calls encouraging activity and ambulatory oxygen use were made**. Tri-axial accelerometers were used during the last week to measure mean daily activity count (steps)
• Patient preference was **identified by questionnaire**

## KEY FINDINGS

• **There was no statistically significant difference in mean daily activity counts when using HomeFill® compared to usual ambulatory oxygen (95% CI, p= 0.85)**
• HomeFill® allows patients to refill oxygen cylinders as needed using a compressor at home and frees them from liquid or gaseous oxygen delivery
• Patient preference and utilization of ambulatory oxygen includes non-clinical aspects, like greater independence
• **Prescription of ambulatory oxygen should be considered at an earlier stage of COPD**

## KEY QUOTES

• "HomeFill® was equivalent to usual provision of ambulatory oxygen and **was preferred by the majority of patients.**"
• "Eighteen (18) patients (62%) elected to keep HomeFill®, of whom 11 previously used LOX as their usual ambulatory oxygen, **mostly because of freedom from deliveries**"
• **"HomeFill® is equivalent to usual ambulatory oxygen in alleviating exercise hypoxaemia"**
• **"Prescription of ambulatory oxygen should be considered at an earlier stage before severe deconditioning"**
• "I really like the fact that you can refill the cylinders at your leisure and **don't have to worry about deliveries**" a patient commented

# KEY ILLUSTRATIONS

**Figure 1**

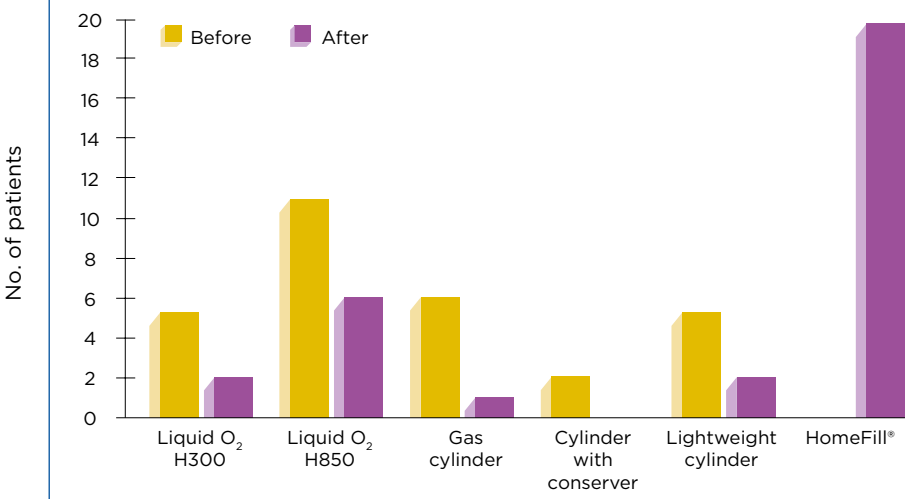



**Figure 1**
Patient's ambulatory oxygen devices use before and after study completion. Eighteen (18) patients elected to keep HomeFill®, mostly because of freedom from deliveries.

**Mean daily activity counts (steps)**

| | Trial arm 1 | Trial arm 2 | Difference |
|---|---|---|---|
| Cohort A<br>N=13 | 22,478<br>(20,112) | 17,124<br>(13,627) | + 5,354 |
| Cohort B<br>N=16 | 41,788<br>(28,906) | 36,740<br>(30,373) | - 5,049 |

**Figure 2**
No statistically significant difference in mean daily activity count was found between the two groups (CI=95%, p= 0.85).

# Invacare® ambulatory oxygen systems

**Unlimited oxygen supply**
A choice of ambulatory systems enabling an unlimited oxygen supply.

**Compliance**
Ambulatory oxygen systems encourage patients to be more compliant with their oxygen therapy.

**Ambulation**
Small portable systems allow greater mobility than other traditional oxygen modalities.

**Independence**
No oxygen deliveries mean increased independence for ambulatory oxygen patients.

**Proven track record**
Over 10 years experience from the world leader in oxygen, with more than 1 000 000 ambulatory patients treated worldwide.

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