# Confidence comes easy with the F&P Eson™ 2 Nasal Mask

## 1.0 Introduction

Obstructive sleep apnea (OSA) is a common sleep disorder affecting up to nine percent of the adult population[1] and is characterized by the periodic collapse of the upper airway during sleep[2]. The standard treatment for OSA is continuous positive airway pressure (CPAP), which consists of pressurized air applied to the nose/mouth via an interface. Adherence to treatment for OSA remains poor, in the range of 30 to 60%[3], despite improvements in technology. Reasons for the intolerance to therapy include: discomfort due to poor mask fit[4], nocturnal awakenings[5], and nasal problems with dryness and congestion[6]. Poor mask fit can result in facial abrasions, nasal discomfort and mouth leak, which causes fluctuations in therapeutic pressure as well as irritation of the eyes and nose. Fisher & Paykel Healthcare (Auckland, New Zealand) has designed a new nasal mask – the F&P Eson 2 (Figure 1).

*Figure 1. The F&P Eson 2 nasal mask*

The primary aim of this randomized study was to evaluate how participants viewed the performance, comfort and ease of use of the F&P Eson 2 mask, and how it compared with the F&P Eson.

## 2.0 Method

### 2.1 Participant selection

Thirty-nine patients with OSA, established on PAP therapy, were recruited into this study. Participants were all sourced by Clayton Sleep Institute (St. Louis, Missouri, USA). All participants provided written informed consent, and the study was approved by IntegReview IRB. Participant inclusion criteria were: age >18 years, a diagnosis of OSA by a practicing physician, is prescribed a PAP therapy (bi-level or continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP)) for OSA and is an existing nasal mask user for > 30 days.

### 2.2 Study design

This investigation was a prospective, randomized, non-blinded, cross-over study. Following informed consent, participants used an F&P ICON™+ CPAP device for 7 days using their usual nasal CPAP mask to provide baseline data. Participants were then randomized to either the F&P Eson or the F&P Eson 2. The first mask was used in the home according to their normal prescription for 7 ± 3 days. Each participant then repeated this procedure using the second mask.

During the second and third visits to Clayton Sleep Institute, participants were asked questions on the masks pre and post use. They then returned the mask and had a final interview. At the end of the study each participant was gifted an F&P Eson mask, if that was their preferred mask over the F&P Eson 2. Those participants who preferred the F&P Eson 2 were asked to use the mask in-home for an additional 3 months to determine whether or not longer-term participant satisfaction remained (Figure 2).

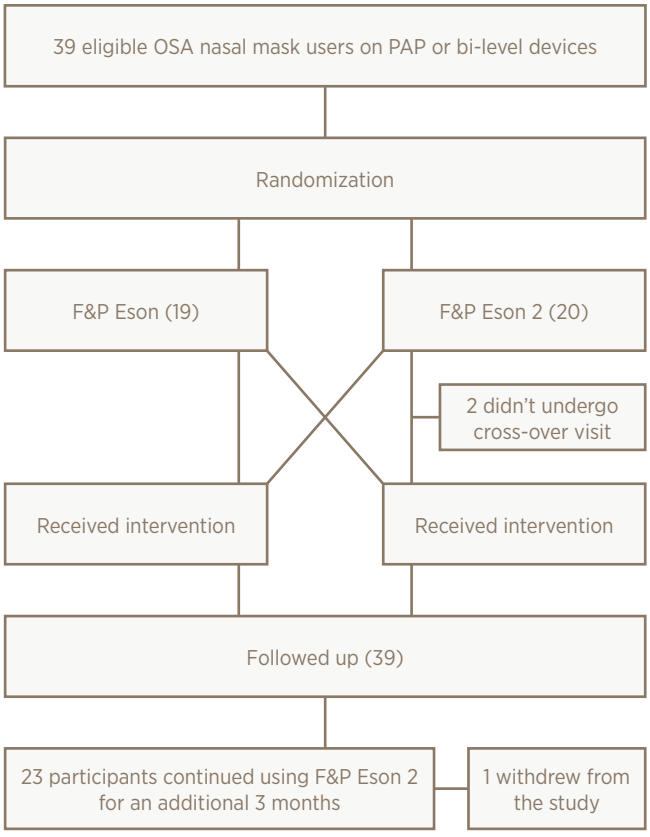



*Figure 2. Flow chart of study protocol*

### 2.3 Measurements

The survey evaluated the following:
the general demographic of participants (age, ethnicity, length of time on therapy, and previous mask used)

- the participants' rating of the F&P Eson 2 in relation to comfort, seal performance (leak), ease of use, seal stability, and noise/air draft performance
- the participants' rating of the F&P Eson 2 in terms of overall fitting and removal of the mask
- the participants' comparison with the F&P Eson 2 to the F&P Eson mask in relation to comfort, effective seal, ease of use, mask stability, and level of noise and air draft
- the participants' comparison with the F&P Eson 2 to their usual mask in relation to overall fitting of the mask, assembly/disassembly and preference of mask for ongoing use with CPAP therapy.

Other measurements that were recorded during the study were: the participants' AHI, average leak and average time on therapy.

### 2.4 Statistical analysis

The ratings used in the survey were based on a five-point Likert scale. These results were then grouped into three categories for ease of analysis. For example, when participants rated mask fit, their responses were grouped as: 1) "very good" and "good"; 2) "neither good nor poor"; and 3) "poor" and "very poor".

The subjective rating of the F&P Eson 2 was analyzed using Chi-square tests based on SPSS 22.0 (SPSS, New York, USA).

A two-tailed p-value of <0.05 was taken to indicate statistical significance.

## 3.0 Results

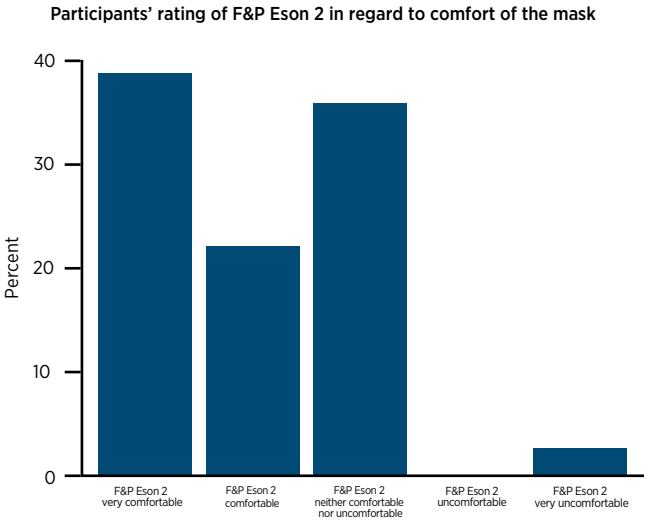
Forty eligible patients were invited to participate in the study. All participants provided written informed consent, 39 of whom were enrolled in the study; one participant was excluded as they did not meet inclusion criteria and two did not attend a visit or only completed one arm of the study.

### 3.1 Participant demographics

| **N** | **39** |
|---|---|
| Average age | 51.44 ± 10.50 |
| Male/Female | 22/17 |
| Ethnicity | 36 Caucasian, 2 African American and 1 Asian |
| Time on CPAP | Less than one year 7<br>One to six years 25<br>Greater than six years 7 |

### 3.2 Participants' ratings of the F&P Eson 2 nasal mask

A total of 61.1% of the participants rated the F&P Eson 2 to be "very comfortable/comfortable" in terms of comfort of the mask (refer to graph below), 82.1% rated it to be "very good/good" for sealing performance, 84.6% and 87.2% rated it very easy/easy for fitting the mask and cleaning the mask, respectively.




Over 90% of participants commented that the noise or draft didn't disturb them or their bed partners during use of the F&P Eson 2.

The assembly and disassembly of the F&P Eson 2 mask was assessed to determine its usability during maintenance activities. More than 97.4% of participants found connecting and disconnecting the following parts of the F&P Eson 2 to be "easy" or "neither easy nor difficult". (See Figure 3 for part references.)

- Disconnect CPAP tube to F; 100%
- Disconnect F to E; 100%
- Remove H from E; 97.5%
- Remove A to B; 97.4%
- Remove C to B; 97.5%

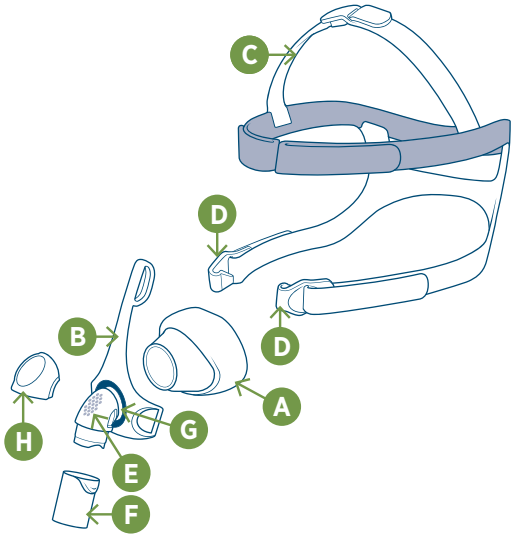



*Figure 3. The F&P Eson 2 nasal mask parts*

### 3.3 Comparison of the F&P Eson 2 with the F&P Eson

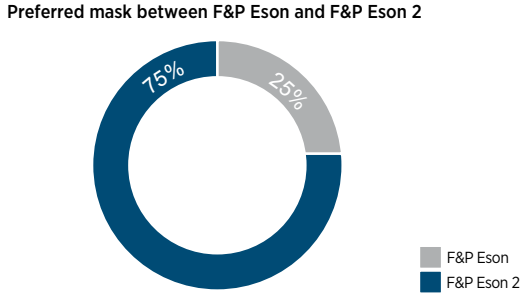
Participants were asked to compare their experience of the F&P Eson 2 with the F&P Eson after 1 week's in-home use on each mask. More than 91% of participants rated the F&P Eson 2 to be equivalent ("neither easier nor more difficult") or superior ("much easier/easier") in

all categories below in comparison with the F&P Eson nasal mask.

1. The F&P Eson 2 fitting was superior or equivalent to the F&P Eson (94.4%)
2. The F&P Eson 2 ease of use was superior or equivalent to that of the F&P Eson (94.4%)
3. The F&P Eson 2 seal performance was superior or equivalent to the F&P Eson (91.6%)
4. All participants found the F&P Eson 2 assembly/disassembly to be superior or equivalent to that of the F&P Eson (100%).

Participants were then asked to compare the F&P Eson 2 with the F&P Eson in regard to stability, leak, satisfaction, noise and draft. More than 88% of participants rated the F&P Eson 2 to be equivalent ("neither good nor poor") or superior ("very good/good") in all categories in comparison with the F&P Eson nasal mask. There were no significant differences found in the ratings for draft performance of the F&P Eson 2 ($p = 0.182$).

Seventy-five percent of participants preferred the F&P Eson 2 over the F&P Eson.




### 3.4 Comparison of the F&P Eson 2 with each participant's usual mask

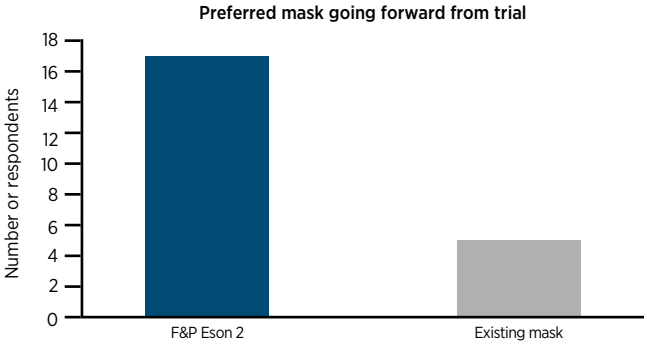
After 1 week's in-home use of the F&P Eson 2, participants were asked to compare their experience with that of their usual mask. More than 83% of participants rated the F&P Eson 2 to be equivalent ("neither easier nor more difficult") or superior ("much easier/easier") in the categories below in comparison with their usual mask.

1. The F&P Eson 2 fitting was superior or equivalent to the participant's usual mask (83.4%) $p = 0.112$ – non-significant
2. The F&P Eson 2 assembly/disassembly was superior or equivalent to the participant's usual mask (88.8%) $p = 0.004$.

### 3.5 Participant's preference

A total of 58.3% of the participants chose the F&P Eson 2 over the F&P Eson (after 1 week's use) and their usual mask (after > 30 days' use).

Of the 23 participants who preferred the F&P Eson 2 as their primary mask going forward, 22 opted to continue using the F&P Eson 2 in-home for an additional 3 months (56.4% of trial participants). Of these participants after 3 months in-home using the F&P Eson 2, 77.3% preferred it over their usual mask.




Subjective feedback from participants was collected and comments such as the following were used to convey their level of satisfaction of the F&P Eson 2 nasal mask:

***The swivel allows the hose to move and not tangle. The seal is very tight and makes the mask very quiet. You don't even realize it's on. — Male, 46 years old***

***I like the way the straps feel on my cheeks. They are soft and smaller. — Female, 50 years old***

## Discussion

Having a mask design that focuses on improving the current state of comfort, ease of use and satisfaction during use is an important factor in achieving the patient's acceptance of CPAP therapy. To continually strive to increase the level of patient comfort, usability and satisfaction with masks is a challenge, especially with nasal masks as there are so many different types available from a wide range of manufacturers.

The F&P Eson 2 mask was easy to fit, clean and adjust. This could have been attributed to the VisiBlue™ features on the mask, which are blue highlights (on the seal, swivel and headgear) that make it simpler, quicker and more intuitive for the participant to connect/disconnect parts when cleaning and these also assist in the orientation of the mask for easy fitting ($p = 0.003$). Although this research did not find a direct association between the VisiBlue feature and the use of the mask, some evidence was gathered in support for color cues on the mask and the usability improvement of the mask. Further research into this subject area is needed. A mask that is easy to fit and is more comfortable for the patient to wear could reduce the time spent by respiratory therapists at the initial fitting and the time involved in providing education. This mask could also be beneficial during CPAP titration studies in-lab due to the usability aspects incorporated in its design. A major limitation of the study is that it was not blinded to the type of mask. Therefore, bias on the part of investigators or even participants cannot be eliminated completely.

In addition, most participants in this study were using nasal masks without a T-piece prior to trialing the F&P Eson and the F&P Eson 2. They associated the benefits

of such a mask with the ability to wear glasses, less mask coverage involved and with the F&P Eson 2 not being so obtrusive on the face. Only two participants in the final interview mentioned they did not prefer the F&P Eson or the F&P Eson 2 due to the T-piece; however, the others attributed the benefits to mask stability and the fact that the T-piece offered the ability to receive effective treatment even while tossing and turning during the night, and minimized mask dislodgement and air leaks. Participants commented that there were fewer leaks in the middle of the night and the mask therapy was quieter. There were comments about less disruption to the bed partner and having had a positive experience with it generally. This resonated well, with 56.4% wanting to continue using the F&P Eson 2 for an additional 3 months. Of those participants who continued using the F&P Eson 2 for an additional 3 months in-home, 77.3% preferred the F&P Eson 2 over their usual mask at the end of 3 months. This demonstrated an overall positive experience with the F&P Eson 2 in a CPAP-established group of participants.

Improving mask leaks is essential for patient comfort as this had previously been reported to be a problem in 63.0% of OSA patients[7]. The feedback from the final interview suggested that there was an improvement in the sealing performance of the F&P Eson 2 compared with the F&P Eson; however, no objective leak measurement showed a difference when compared with other masks ($p = 0.297$) when a Paired Samples Test was applied in the analysis. Maintaining an effective seal during use is an integral part of the mask design process, with comfort and fit determining whether or not a mask provides the best chance of therapy success. Mask development in this area continues, in an attempt to minimize irritation and discomfort of the seal around the nose.

This is in line with Gregoretti et al.[8], who evaluated patient comfort, skin breakdown and eye irritation when comparing a conventional face mask with a prototype face mask during noninvasive ventilation. Overall, they found patient comfort was higher for the prototype mask than for the conventional mask after 24 hours' use and eye irritation was absent for both the conventional mask and prototype mask after 24 hours' use and didn't differ significantly after 48 hours of use. There was no notable difference between the two masks and time on ventilation.

In conclusion, this study has shown that ongoing incremental design improvements in the F&P Eson 2 compared with the F&P Eson can improve the satisfaction of an already high-performing nasal mask, being the F&P Eson. For patients using PAP therapy, the F&P Eson 2 offers a good chance of ongoing therapy adherence. Given the potential cost of untreated OSA to healthcare systems, it is important that enhancements to current mask features and technologies continue to ensure the best-possible care can be provided to those who suffer from OSA and that adherence to CPAP therapy is improved on an ongoing basis.

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