

Patient Pain Points in Therapy

How F&P Solo™ offers a simple solution and a clinical perspective on why the Mask Matters Most™

Challenges with Adherence

Obstructive sleep apnea (OSA) is a common form of sleep-disordered breathing characterized by frequent arousal due to upper airway collapse during sleep.^{1,2} Current estimates suggest that OSA affects nearly one billion individuals worldwide, but only 20% of suspected cases are clinically diagnosed.^{3,4} If untreated, OSA can lead to serious medical complications such as hypertension and cardiovascular disease, owing to its pro-inflammatory nature.⁵ The primary treatment for OSA, positive airway pressure (PAP) therapy, involves the delivery of pressurised air to the upper airway via a mask.⁶ PAP therapy effectively maintains airway patency during sleep, and with consistent use, has been shown to significantly reduce excessive daytime sleepiness and disease severity.^{3,6,7}

Despite the favorable health outcomes linked to PAP therapy, long-term compliance remains subpar, with more than 50% of patients choosing to abandon treatment within the first year of initiating use.^{8,9} Lack of adherence is largely driven by comfort and performance issues related to wearing a mask. Patients often complain about lingering facial marks, skin breakdown, pressure sores, irritation, and leak into the eyes, because of overtightening or improper mask fit. Some also report dissatisfaction with the overall complexity of the PAP therapy system.¹⁰⁻¹² Among new patients, about 19% switch masks during the first year of treatment, although most switches occur in the first two weeks. The chances of treatment abandonment increase greatly with mask switching behavior.^{13,14}

Fisher & Paykel Healthcare (F&P) recognizes that compliance patterns are established early, and for this reason, believe that the challenges patients face in acclimatizing to treatment can be addressed through considered mask design and an enhanced user experience. A study conducted by F&P in the United States found that healthcare professionals believe the mask is the single most important piece of equipment in the PAP therapy system.¹⁵ Results from an independent survey of patients revealed that 76% of those who discontinue PAP therapy cite mask discomfort as a key reason for inconsistent treatment use. Moreover, 58% of patients who decided to stop treatment said if their mask was more comfortable they might be encouraged to use PAP therapy again or more frequently.¹¹

Mask Selection and Fit

Although there is limited empirical evidence to support the application of clinical techniques which consistently alleviate discomfort and unintentional leak, research suggests that ensuring optimum mask fit during setup is a critical part of ensuring a patient's success on their treatment journey.¹⁴ Mask performance and comfort are intricately linked. Overtightening a mask to combat leaks from the cushion puts unnecessary pressure on certain parts of the face. This can cause discomfort with prolonged use. Adherent patients experience significantly less leaks compared to non-adherent patients. This is unsurprising, given 65% of patients report that leaks frequently disrupt their sleep in many ways, including the noise that results from breaking a seal on the face.¹⁴ Achieving the right fit with a mask is also challenging due to the diverse range of craniofacial features among patients. Many masks require a multi-step fitting process to accommodate this variability.¹⁰

A recent meta-analysis evaluating different mask types indicated that nasal and nasal pillow masks provide more efficacious PAP therapy when compared to oronasal masks. This was attributed to the compromising cumulative effects of oronasal mask use, which may displace the mandible, tongue, and soft palate posteriorly, thus decreasing airway patency. Oronasal masks can be useful in patients with mouth leak or severe nasal congestion, but typically offset these issues by delivering a higher therapeutic pressure.⁵ This is why nasal and nasal pillow masks are usually the first choice for treatment.¹⁶ However, use of nasal and nasal pillows masks may introduce a unique set of challenges for patients if they encounter nostril sensitivity and nasal discomfort due to poor fit.¹⁴

Compliance of any kind requires buy-in from the patient, particularly among those newly diagnosed. Some level of the existing dissatisfaction with PAP therapy is likely due to a lack of patient empowerment or reduced confidence in navigating treatment. F&P's Mask Matters Most philosophy targets the three pillars of successful treatment: initial setup and support, performance, and comfort - to focus attention on challenges with adherence from a mask-centric perspective.

A Targeted Solution

While it is the role of the prescribing healthcare professional to consider which mask will work best, having access to high-performing mask options to suit the individual needs and preferences of patients is important. The F&P Solo mask has been designed to overcome many of the challenges associated with starting therapy. Following years of extensive research and development, F&P created a mask that addresses what has always been a paradox – well-fitted masks are often complicated to use, but simple masks might fit poorly.^{11,12,15} To achieve both simplicity and good fit, the F&P Solo mask distinguishes itself with its pioneering AutoFit™ headgear. Both nasal and nasal pillows cushion mask configurations feature F&P's novel AutoLock™ technology. This forms the basis of a patented headgear component which allows patients to fine-tune fit effortlessly with a touch once the mask is placed over the head.

To simplify setup and reduce the risk of overtightening, AutoFit replaces conventional headgear adjustment systems, like hook-and-loop fasteners, clips, and magnets, with a simple, safe, and effective headgear adjustment mechanism. Figure 1 shows F&P Solo's proprietary headgear technology in action. AutoFit enables patients to tailor headgear fit depending on their preference, by pulling the headgear to loosen or touching the headgear to tighten. The AutoLock mechanism continues to hold the mask securely in place on the face and immediately responds to any movement or repositioning during sleep. F&P's next generation Dynamic Support Technology™, in conjunction with the AutoFit headgear, helps reinforce the overall stability of the mask.



Figure 1. AutoLock technology in the F&P Solo headgear

Part of the burden placed on new patients is that they are required to quickly acquire the ability to properly fit their mask on a night-by-night basis to comply with PAP therapy. Albeit several factors can make this difficult, including poor dexterity or eyesight, the need to constantly adjust fit, as well as managing leak and discomfort, F&P Solo may help reduce this learning curve by simplifying setup early into treatment use. The intuitive AutoLock mechanism housed in the headgear requires minimum force to ensure a secure fit, the responsiveness of the mask during sleep confers stability during restlessness and freedom to move in bed, and the low-profile cushion allows patients to enjoy an unobstructed view without the claustrophobic feeling sometimes linked to wearing a mask. The challenge for F&P was designing a mask with innovative qualities to improve usability without sacrificing comfort and performance. F&P Solo is as easy to setup for patients as it is to wear.

Measuring Success

F&P conducted a clinical validation to assess the performance and safety of the F&P Solo mask. A representative demographic mix of 91 participants who use PAP therapy were recruited across two sites in the United States as part of a single-arm, non-randomized, non-blinded investigation. Of these, 45 used the F&P Solo Nasal mask and 46 used the F&P Solo Pillows mask. Once enrolled in the investigation, participants were fitted with the F&P Solo mask by a healthcare professional, which they used in place of their usual PAP therapy mask for two weeks. Feedback collected from participants after this period highlighted their unique experiences and level of satisfaction with the F&P Solo mask. Details of the investigation design and timeline are presented in Figure 2.

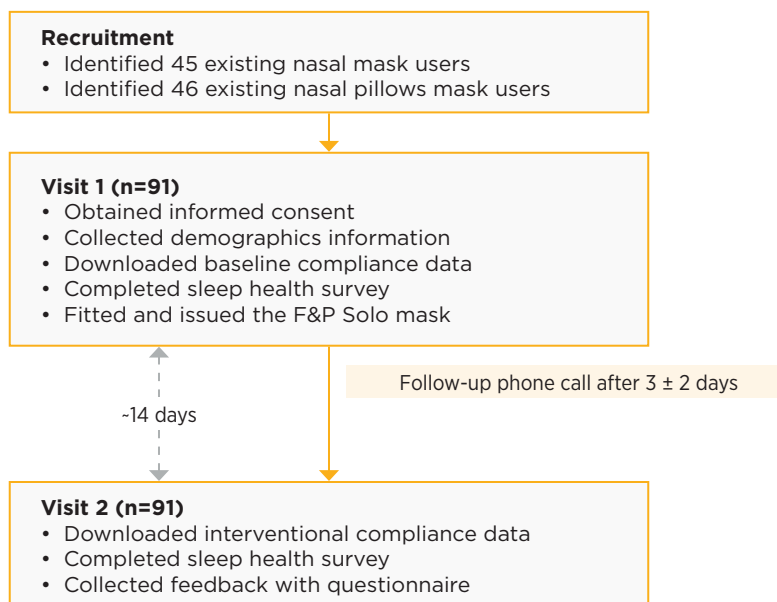


Figure 2. Investigation design and timeline

All participants were screened during the recruitment process per the inclusion and exclusion criteria to ensure they met the necessary health and safety requirements for enrolment. These criteria included prescription of PAP use by a physician, adequate treatment compliance (i.e., ≥ 4 hours per night for 70% of nights), and experience using a nasal, sub-nasal, or nasal pillows mask.

Qualitative and quantitative measurements were collected to confirm treatment efficacy. Facilitated interviews were also conducted to gain a deeper understanding of participant experiences. Performance metrics comprised of static leak tests, compliance reports from devices, and a questionnaire covering subjective experience with leak. Comfort assessments were conducted through questionnaire feedback evaluating cushion and headgear comfort, and freedom of movement. User experience was assessed with questionnaire feedback regarding the ease of mask assembly, disassembly, and cleaning. Finally, therapeutic efficacy was assessed with the Epworth Sleepiness Scale and Apnea-Hypopnea Index data from compliance reports.

F&P Solo Pillows Results

The F&P Solo Pillows mask proved to have high performance in the validation.

- 89% of participants reported that the mask stayed in place during the night.¹⁷
- 93% of participants rated the cushion performance as good or very good.¹⁸

The comfort of the F&P Solo Pillows mask was rated highly among participants in the validation.

- 93% of participants found the mask noise acceptable to sleep with.¹⁹
- 87% of participants found the mask to be comfortable overall.²⁰ More specifically, 80% of participants rated the cushion as either comfortable or very comfortable to wear, both under the nose and inside the nostrils.^{21,22}
- 98% of participants were able to sleep in their preferred position.²³

The F&P Solo Pillows mask demonstrated successful setup and fitting results. Most participants were able to self-setup, fit, adjust, and remove the mask with ease. This is supported by the following results.

- 93% of participants were able to make mask adjustments in the dark, and rated the process as easy or very easy.²⁴
- 96% of participants rated the process of initial setup to be simple or very simple, with 93% of participants reporting that the overall fitting experience was either easy or very easy.^{25,26}
- 100% of participants were able to adjust the mask and found it to be a straightforward process.²⁷ Additionally, 87% of participants could do so with just one hand, finding it easy or very easy.²⁸

F&P Solo Nasal Results

The performance of the F&P Solo Nasal mask was supported by the following results.

- 80% of participants reported that the mask stayed in place during the night.²⁹
- 91% of participants rated the cushion performance as good or very good.³⁰

The comfort of the F&P Solo Nasal mask was rated highly among participants in the validation.

- 93% of participants found the mask noise to be acceptable to sleep with.³¹
- 93% of participants found the mask to be comfortable overall.³²
- 82% of participants were able to sleep in their preferred position.³³

Overall, participants were able to fit the F&P Solo Nasal mask independently and correctly.

- 91% of the participants were able to make mask adjustments in the dark and rated the process as easy or very easy.³⁴
- 93% of participants reported that the overall fitting experience was either easy or very easy.³⁵ Additionally, 89% of users described the initial setup process as simple or very simple.³⁶
- 98% of participants found the process of adjusting the mask by pushing or pulling the mask towards or away from the face to be easy or very easy.³⁷

The Patient Journey

Initial setup and support

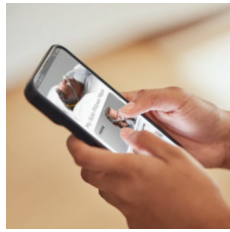
Once prescribed, patients usually receive face-to-face education about PAP therapy and personalized mask fittings, with the opportunity to trial treatment equipment in a sleep lab environment under the supervision of an experienced sleep technologist or physician. An F&P internal study found that providing easy-setup masks was the number one need for durable medical equipment providers to enhance their operations by enabling remote management of certain aspects of care and reducing the need for unscheduled in-person visits.³⁸ The F&P Solo mask offers a practical solution by leveraging advanced technology to benefit both patients, healthcare professionals, and durable medical equipment providers.³⁸ Its innovative design can help address shared challenges experienced across a patient's journey. The AutoFit headgear system aids setup and adjustment with a single touch, instructional material supports patient education, and the F&P myMask™ mobile app is designed to give patients confidence when starting treatment. F&P aims to offer a well-rounded solution, as demonstrated in Figure 3, that improves PAP therapy accessibility and adherence, enhances the patient experience, and will increase operational efficiency for providers.

Performance

The majority of patients have experienced mask-related issues with PAP therapy at some point in their OSA journey. A common patient complaint is poor mask fit, often resulting from excessive overtightening of the mask.¹⁴ The F&P Solo mask, featuring the AutoLock technology, provides an innovative solution to this problem. It simplifies setup, allowing patients to easily adjust the fit with a single touch, while also dynamically responding to movement during sleep and preventing overtightening. AutoLock technology permits patients to make fine-tuned adjustments directly in front of their face without having to reach to the sides of the head. This helps maintain cushion stability and eliminates the need for fitting corrections which can disrupt sleep. Patient input is also intuitive, simply requiring them to touch the mask where needed to customize their individual fit and resolving any issues with minimal effort. This was supported by findings from the clinical validation, with the overall fitting experience being reported as either easy or very easy in 93% of F&P Solo Nasal and 96% of F&P Solo Pillows. Overall, participants who wore F&P Solo had positive experiences with the setup fitting process and achieving an appropriate seal, confirming that it is possible for patients to set themselves up with minimal assistance and then easily fine-tune the mask during ongoing use.

Comfort

F&P understands that the PAP therapy system consists of many complex components but believe that these should be designed to work together to offer the most comfortable, trouble-free experience for patients. Mask discomfort is a persistent complaint among both new and experienced patients who use PAP therapy.¹⁴ F&P Solo features Dynamic Support Technology, allowing freedom of movement while keeping the cushion comfortably in place. This was observed in the clinical validation, with 80% of participants noting the F&P Solo Nasal mask stayed in place overnight, with high reports of overall mask comfort in 93% of participants. Nasal pillows masks are associated with higher rates of complaints about irritation and nostril discomfort. This was not a concern for 80% of participants who rated the F&P Solo Pillows cushion as comfortable to wear under the nose and inside the nostrils.



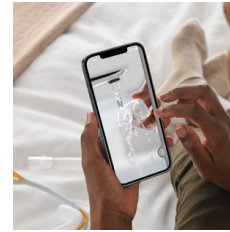
Setup with the F&P myMask™ App

For an enhanced experience, F&P myMask supports your patients with mask setup and fitting.



User-friendly packaging

Step-by-step pictorial instructions provides confidence to set up the mask independently.



F&P myMask support

F&P myMask helps with fitting, cleaning and troubleshooting. Support when it's needed most.

Figure 3. Simplifying the mask setup experience

At F&P, masks are designed with usability, performance, and comfort in mind, and as part of a Care by Design™ approach, which is centered on satisfying the needs and expectations of patients. This philosophy extends to our range of masks and setup solutions, which ensure a successful early experience with PAP therapy, and one that is comprehensive enough to foster a patient's transition from novice to proficient user. This begins with achieving an appropriate mask fit. We believe that getting this right for patients will make ongoing treatment management easier for healthcare professionals. F&P Solo, pictured in Figure 4, combines years of relentless innovation and cutting-edge components to usher in a new era of PAP therapy masks. The results from the validation of the F&P Solo Nasal and F&P Solo Pillows confirmed that the masks are high-performing, comfortable, and easy to use, while overcoming the persistent issues faced by patients and healthcare professionals.



Figure 4. F&P Solo is high-performing, comfortable, and easy to use

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17. 41 out of 46 participants indicated the F&P Solo Pillows mask stayed in place during use throughout the night. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
18. 43 out of 46 participants rated the cushion performance of the F&P Solo Pillows mask as “good” or “very good”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
19. 43 out of 46 participants rated the noise from the F&P Solo Pillows mask acceptable to sleep with. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
20. 40 out of 46 participants rated the F&P Solo Pillows mask as comfortable overall. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
21. 37 out of 46 participants rated the F&P Solo Pillows mask cushion as ‘comfortable’ or ‘very comfortable’ inside the nose. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
22. 37 out of 46 participants rated the F&P Solo Pillows mask cushion as ‘comfortable’ or ‘very comfortable’ to wear. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
23. 45 out of 46 participants indicated they were able to sleep in the preferred sleeping position with the F&P Solo Pillows mask. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
24. 43 out of 46 participants rated their experience with adjusting the F&P Solo Pillows mask in the dark as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
25. 43 out of 46 participants rated their overall fitting experience with the F&P Solo Pillows mask as “simple” or “very simple”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
26. 44 out of 46 participants rated their experience with initially setting up the F&P Solo Pillows mask as “simple” or “very simple”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
27. 46 out of 46 participants indicated they were able to adjust the F&P Solo Pillows mask by pushing and pulling the mask toward and away from their face. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
28. 40 out of 46 participants rated their experience with adjusting the F&P Solo Pillows mask with one hand as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
29. 36 out of 45 participants indicated the F&P Solo Nasal mask stayed in place during use throughout the night. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
30. 41 out of 45 participants rated their experience with the F&P Solo Nasal cushion performance as “good” or “very good”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
31. 42 out of 45 participants rated the noise from the F&P Solo Nasal mask acceptable to sleep with. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
32. 42 out of 45 participants rated the F&P Solo Nasal mask as comfortable overall. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
33. 37 out of 45 participants indicated they were able to sleep in the preferred sleeping position with the F&P Solo Nasal mask. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
34. 41 out of 45 participants rated their experience with adjusting the F&P Solo Nasal mask in the dark as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
35. 42 out of 45 participants rated their overall fitting experience with the F&P Solo Nasal mask as “simple” or “very simple”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
36. 40 out of 45 participants rated their experience with initially setting up the F&P Solo Nasal mask as “simple” or “very simple”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
37. 44 out of 45 participants rated their experience with adjusting the F&P Solo Nasal mask by pushing or pulling the mask towards or away from the face as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 91 participants in the United States, 2022.
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