

Less is Best™: How F&P Nova Micro™ encourages a natural sleep experience and a clinical perspective on why mask selection is key

The Challenge with Long-Term 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 pressurized air to the upper airway via a mask.⁶ Successful treatment of OSA with PAP therapy is achieved by long-term, continuous adherence. However, patient adherence to therapy remains sub-optimal, despite the improved health outcomes linked to long-term PAP therapy use. A patient's early experience with PAP therapy is shown to be one of the strongest predictors of long-term use, and it is estimated that within the first year of beginning PAP therapy more than 50% of patients will abandon treatment.⁷ Further, long-term adherence to PAP therapy can be determined as early as three days after treatment initiation, which indicates the criticality of ensuring the most appropriate equipment for the patient is provided as early as possible.⁸ To encourage a positive start to using PAP therapy, it is important that a mask is able to easily assimilate into a patient's individual lifestyle, while still meeting their therapeutic requirements and expectations of healthcare professionals.

The Mask Matters Most™

Poor adherence continues to be primarily motivated by mask-related issues as the mask is the component of the system that a patient most intimately interacts with. Common complaints among patients who have discontinued PAP therapy include mask discomfort, pressure sores, unintentional mask leak, and claustrophobia, largely driven from improper mask fit and overtightening.⁹⁻¹¹ Many mask types exist to accommodate different patient requirements and expectations. More recently, the desirability of nasal pillows masks for patients with OSA is increasing due to their minimal facial contact area, less obtrusiveness and reduced leakage rates, leading to higher initial mask acceptance rates.^{12,13} However, challenges with adherence remain, as patients indicate that mask movement during the night can result in nostril soreness and irritation.

Our Solution

In response to the recognized barriers to PAP therapy adherence and in an attempt to address the common complaints reported by users of nasal pillows masks, F&P has developed Nova Micro, our smallest and lightest mask** to date (shown in Figure 1). Through an iterative, multi-years long process, F&P Nova Micro focuses on creating a natural sleep experience by reducing the surface contact area on the face, simplifying the headgear adjustment process and creating a soft, inflating seal which supports freedom of movement while preventing leak during sleep.



Figure 1. F&P Nova Micro is F&P's smallest and lightest mask yet.

Measuring Success

F&P conducted a clinical validation to assess the performance and safety of the Nova Micro mask. A total sample of 39 participants who were prescribed and compliant to PAP therapy and had been using a nasal pillows mask for at least three months prior were enrolled in a single-arm, non-randomized, open-label study conducted in the United States. Once enrolled in the investigation, participants were fitted with a Nova Micro mask by a healthcare professional, which they then used in place of their usual PAP therapy mask for two weeks. Participants were then interviewed to collect feedback on their experience using the Nova Micro mask, covering topics such as performance, comfort, and ease of use. Details of the investigation timeline are presented in Figure 2.



Figure 2. Timeline summary of the validation investigation of the F&P Nova Micro mask

Participant Demographics and Measures

All enrolled participants were screened during the recruitment process in accordance with the inclusion and exclusion criteria to ensure they met the necessary health and safety requirements for enrollment. 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 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 using a combination of the Epworth Sleepiness Scale and Apnea-Hypopnea Index (AHI) data from compliance reports. No participants withdrew during the investigation. However, one participant was excluded from the analysis as they did not wear the mask at any point over the two-week period.

Demographics	
Gender	
Male	57.8%
Female	42.2%
Ethnicity	
Caucasian	91.1%
African American, Asian, Hispanic, and Polynesian	8.8%
Therapy type	
CPAP	82.2%
APAP	16.6%
BPAP	2.2%

Figure 3. Demographics of clinical validation study participants.

Validation Results

The F&P Nova Micro mask proved to have high performance in the validation.

- 100% of participants rated the overall performance of the mask as good or very good.¹⁴ More specifically, 87% of participants rated the overall stability of the mask as stable or very stable.¹⁵
- 97% of participants rated their ability to move around in bed while wearing the mask as easy or very easy.¹⁶
- 97% of participants were able to sleep in their preferred sleeping position.¹⁷
- 97% of participants found the mask noise acceptable to sleep with.¹⁸

The comfort of the F&P Nova Micro mask was rated highly by participants in the validation.

- 95% of participants rated the mask's overall comfort as comfortable or very comfortable.¹⁹ More specifically, 97% of participants rated the feel of F&P Nova Micro pillows in their nose as soft or very soft²⁰ while the same percentage of participants rated the Nova Micro headgear as comfortable or very comfortable.²¹
- 95% of participants found the weight of the mask to be light or very light²² while 90% of participants rated the size of the mask as small or very small.²³
- 92% of participants found the inflation of the pillows to be gentle or very gentle.²⁴
- 87% of participants found the pillows cushion contact in their nose to be comfortable or very comfortable.²⁵

The F&P Nova Micro demonstrated delivered a positive user interactive experience in the validation.

- 100% of participants rated the initial mask set-up process as simple or very simple²⁶ with 95% of participants rating their ability to adjust the headgear as easy or very easy.²⁷
- 97% of participants found that the mask did not obstruct their field of view while wearing the mask.²⁸
- 95% of participants found the F&P Nova Micro mask to be compact or very compact.²⁹

Discussion

The choice of PAP therapy mask is a key predictor of treatment efficacy and patient adherence. Common mask-related side effects that interfere with a patient's acceptance to PAP therapy mask include: discomfort, unintentional mask leak, irritation, and claustrophobia.^{30,31} Long-term PAP therapy adherence can be determined as early as three days from therapy initiation; therefore selecting the correct mask the first time can encourage a consistent pattern of adherence.³² Nasal pillows masks have been found to be more comfortable, produce less side effects and improve overall satisfaction to PAP therapy.^{13,33} More recently, studies have suggested that mask prescription should consider focusing on nasal and nasal pillows masks as the first-choice management.³⁴ F&P Nova Micro is a small nasal pillows mask that provides a natural sleep environment for PAP therapy mask users through the lightweight and soft MicroPillows™ cushion. Although the size of the mask is very small, the comfort, stability, and performance of F&P Nova Micro was not compromised. This was supported in the investigation as participants who used F&P Nova Micro mask provided high ratings for its overall leak performance, stability and comfort. At the study's conclusion, most individuals indicated they would like to continue using F&P Nova Micro as their primary PAP mask.³⁵

A Natural Sleep Experience

Successful treatment with PAP therapy requires a patient to adapt to a lifelong change from their pre-diagnosis sleep routine. It has been found that disruptions to an individual's natural sleep environment can lead to increased stress and irritability levels, sleep fragmentation and poor sleep quality.³⁶ To overcome the common mask-related risk factors of sleep disturbance, F&P Nova Micro's soft, lightweight cushion, in combination with the petite total size of the mask, led to trial participants noting they did not feel the mask on their face during the night. This was supported with 95% of participants describing the weight of the F&P Nova Micro mask as light or very light and 90% of participants describing the size of F&P Nova Micro as small or very small. Noise is a common complaint by patients using PAP therapy which leads to sleep disturbance.³⁰ Results from this investigation concluded that the noise from F&P Nova Micro was not disruptive to sleep as 97% of participants rated the noise of F&P Nova Micro while sleeping as quiet or very quiet.

Performance

Unintentional mask leak is a side effect frequently experienced by PAP therapy users by reason of poor mask fit and instability during movement in bed.^{30,37} PAP therapy mask performance is defined by unintentional leak. By the end of the investigation, 100% of participants rated the overall performance of F&P Nova Micro as good or very good. F&P Nova Micro enables high performance with the easy, dual-sided headgear adjustment which allows users to fine-tune the headgear on each side of their face. This was highlighted with 95% of participants rating their ability to adjust the headgear as easy or very easy. In this investigation, 95% of participants rated F&P Nova Micro as compact or very compact. The design intent of the dual-sided headgear was to be easy to fit and adjust, while preserving a clear field of vision. Freedom of movement is a significant contributor to mask satisfaction and, therefore, the stability of F&P Nova Micro is an important reflector of satisfaction and performance. F&P Nova Micro ensures freedom of movement in almost all instances, with 97% of participants rating their ability to move around in bed while wearing the F&P Nova Micro as easy or very easy. Despite this, mask stability was firmly established: 87% of participants rated the overall stability of F&P Nova Micro as stable or very stable. Moreover, ease of fit was proven by all participants in the investigation with 100% rating the process of initially setting up the mask as simple or very simple. Overall, F&P Nova Micro's compact size, dual-sided headgear and ease of fitting proved to be very successful with participants, and that stability and performance were not compromised.



Comfort

Mask comfort is one of the most significant determinants of long-term PAP therapy adherence.¹⁰ F&P Nova Micro features a soft MicroPillows cushion, which nestles gently within the nostrils and inflates to conform to the patient's nose. The benefits of this design feature were successfully confirmed by 97% of participants who rated the feel of F&P Nova Micro mask in their nose as soft or very soft. This was further supported by 92% of participants who rated the inflation of F&P Nova Micro as gentle or very gentle. The minimal size and design of F&P Nova Micro promotes comfort as 97% of participants stated that they were often or always able to sleep in their preferred sleeping position, which further highlights the support for freedom of movement, and encouraging a natural sleep environment, as previously discussed.

The Mask Matters Most Philosophy

At F&P, masks are designed with usability, performance, and comfort in mind, as part of our Care by Design™ approach, which is centered on satisfying the needs and expectations of patients. This philosophy extends to our range of masks and set-up 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 Nova Micro, pictured in Figure 4, is the result of years of dedication to designing a nasal pillows mask that addresses the common complaints reported by users in this category of mask.

The results from the validation of the F&P Nova Micro confirm that the mask is high-performing, comfortable, and easy to use, while overcoming the persistent issues faced by patients and healthcare professionals.



Figure 4. F&P Nova Micro

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16. 38 out of 39 participants rated their ability to move around in bed while wearing the F&P Nova Micro mask as “very easy” or “easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 39 participants in the United States. 2022.
17. 38 out of 39 participants stated they were “always” or “often” able to sleep in their preferred sleeping position while using the F&P Nova Micro mask. Internal validation trial conducted by Fisher & Paykel Healthcare on 39 participants in the United States. 2022.
18. 38 out of 39 participants rated the noise of the F&P Nova Micro mask as “very quiet” or “quiet”. Internal validation trial conducted by Fisher & Paykel Healthcare on 39 participants in the United States. 2022.
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21. 38 out of 39 participants rated the F&P Nova Micro mask headgear as “very comfortable” or “comfortable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 39 participants in the United States. 2022.
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