

Translating Design into Real-World PAP Therapy Use

From Efficacy to Adoption: The Role of the Mask and PAP Therapy

Obstructive sleep apnea (OSA) is a common form of sleep-disordered breathing primarily managed with positive airway pressure (PAP) therapy. Despite PAP therapy's proven effectiveness for symptom relief and mitigation of cardiovascular risk, more than 50% of patients discontinue therapy within the first year, with mask-related issues cited as a leading cause.¹ Notably, a patient's long-term PAP therapy adherence pattern can be predicted within as early as the first 72 hours of therapy initiation, highlighting the narrow window during which a positive initial therapy experience is crucial.² Common challenges such as mask instability or leak with positional change, noise or air draft, and visual intrusion can disrupt sleep and influence early discontinuation.³ Within this context, the mask plays a critical role in shaping a patient's comfort, confidence and willingness to persist with PAP therapy.

While PAP therapy delivers pressurized air at a therapeutic level to stabilize the upper airway, sustained use depends on how well the therapy is integrated within a patient's real-world sleep environment. Factors like bedtime routines, preferred sleeping positions, room noise and the presence of a bed partner all shape the lived experience for patients on PAP therapy. The Fisher & Paykel Healthcare (F&P) Nova™ Nasal was developed to address these influential factors by aligning mask design with the reality of diverse sleep routines. By focusing on stability during movement, minimizing noticeable sound and air draft, and reducing the physical load on the nasal bridge, the F&P Nova Nasal supports a seamless integration of PAP therapy into patients' sleep routines.⁴ Recognizing that PAP therapy often extends beyond the individual patient, F&P also considered the broader sleep context, including the role of bed partners. Bed partners are frequently the first to observe the symptoms of OSA such as snoring, pauses in breathing or fatigue, and they often experience sleep disruption themselves. Their perceptions of noise and air draft along with their quality of sleep can influence relationship dynamics and patient motivation to continue PAP therapy. Incorporating bed partner needs and expectations into mask design therefore represents an important, yet often overlooked, dimension of creating PAP interfaces that assimilate effectively into real world sleep environments.

Our Philosophy: *The Mask Matters Most*™

The mask is the primary point of contact between a patient and PAP therapy, and therefore plays a pivotal role in shaping both patient experience and adherence patterns.^{1,5} Lingering facial marks, skin irritation, unintentional leak, claustrophobia and disturbance from noise or air draft are mask-related problems that can affect the patient's likeliness to continue therapy as well as the comfort of their bed partner.^{1,3} F&P has distilled these insights into the Mask Matters Most™ philosophy, which highlights three interdependent pillars for successful treatment and adherence: initial setup and support, performance and comfort. Initial setup and support emphasize appropriate mask selection, fit and guidance from the first nights of therapy, when adherence patterns are established.² Performance focuses on stable therapy delivery during sleep, including effective control of leak, noise and air draft across sleeping positions. Comfort reflects the wearability that encourages patients to persist with nightly use over time. These pillars provide a foundation for designing PAP masks that integrate more effectively into real world sleep environments and support sustained therapy use. Within this framework, PAP therapy mask design represents an ongoing opportunity to better align established mask categories with the evolving demands of natural sleep.

In comparative and observational studies, nasal masks demonstrate greater patient tolerance to therapy than oronasal options.⁶ Over-the-nose nasal masks, the first widely used PAP therapy masks, form a well-established category characterized by a stable nasal seal with a relatively limited facial contact area. This tolerance is clinically meaningful during sleep, where movement and changes in mouth posture can exacerbate leak, pressure points and perceived noise. As a proven and widely adopted interface category, over-the-nose nasal masks present opportunities for refinement, particularly in supporting stability during movement, minimizing sensory disturbance and improving integration into diverse sleep routines.

Our Solution

Based on F&P's established over-the-nose design ethos, the F&P Nova Nasal incorporates a refined cushion profile which builds on RollFit™ principles, structured stability arms with SwingFit™ headgear for easy "swing-on" motion and a washable diffuser designed to minimize expelled air draft. These enhanced features aim to target three recurring drivers of PAP therapy discontinuation – positional stability, perceived noise and visual intrusion – to support a more seamless integration into real-world sleep and shared bedrooms.

The F&P Nova Nasal mask was engineered to address fit, comfort, leak and noise through the following complementary features:

- SwingFit headgear and structured side arms: allows users to simply anchor the cushion on the nose, swing the headgear around their head and secure with one click. The headgear naturally aligns to the frame for easy fastening, including in the dark.
- RollFit soft cushion: RollFit cushion and the pivoting clips conform to the user's nose, rolling with movement to help prevent leaks, regardless of their preferred sleeping position and maintaining a clear field of view.
- Washable diffuser: minimizes noise and draft, supporting a restful night's sleep for both the user and their bed partner.
- Supportive features: optional tube clip and AirEdge™ fabric for comfort and fewer facial marks.



Figure 1. F&P Nova Nasal with the tube up.



Figure 2. F&P Nova Nasal with the tube down.

Measuring Success

The clinical validation for the F&P Nova Nasal mask was conducted in the United States as a single-arm, non-randomized, open-label investigation. A representative population of 43 PAP therapy users participated and substituted their usual over-the-nose nasal mask with the F&P Nova Nasal mask for a two-week period, following fitting conducted by a healthcare professional.

Table 1. Demographics of clinical validation participants

Demographics	
Gender	
Male	60.0%
Female	40.0%
Ethnicity	
Caucasian	88.0%
African American	12.0%
Therapy Mode	
CPAP	11.6%
APAP	83.7%
BPAP	4.7%

Participant feedback was gathered through interviews and questionnaires which provided insights into their experience using the F&P Nova Nasal mask, covering topics such as performance (leak/seal), comfort, usability, and noise and air draft. Therapeutic efficacy, evaluated by a combination of Epworth Sleepiness Score (ESS) and Apnea-Hypopnea Index (AHI) data, was collected also. The partner cohort (n = 20) assessed bed partner perceptions on sleep quality, noise and air draft. Details of the clinical validation timeline are presented in Figure 1 below.

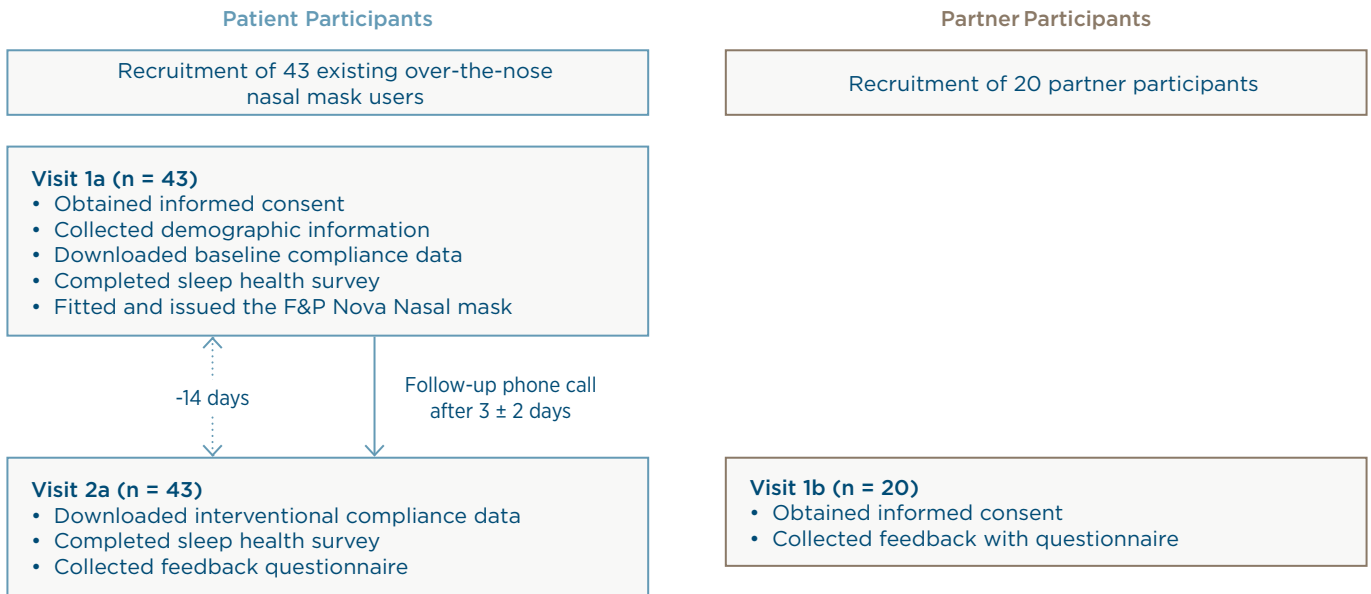


Figure 3. F&P Nova Nasal mask clinical validation timeline

Clinical Validation Results

The F&P Nova Nasal mask successfully demonstrated high performance and a stable seal.

- Overall seal: 86% of the participants rated the overall seal performance as good or very good.⁷
- Stayed in place overnight: 91% of the participants rated the overall stability as stable or very stable.⁸
- Preferred sleeping position: 98% of the participants were often or always able to sleep in their preferred sleeping position.⁹

Participants rated the F&P Nova Nasal mask highly for comfort in the clinical validation.

- Overall comfort: 95% of the participants rated the overall comfort of both the mask and the headgear as comfortable or very comfortable.^{10,11}
- Cushion comfort: 93% of the participants rated the comfort of the RollFit cushion as comfortable or very comfortable.¹²
- Field of view: 84% of the participants rated their field of view as clear or very clear.¹³

The F&P Nova Nasal mask provided a lasting positive experience to participants in the clinical validation.

- Intuitive setup with SwingFit: 91% of the participants rated the process of putting on the mask using SwingFit as intuitive or very intuitive; 98% of the participants rated taking off the mask as easy or very easy; 81% of the participants rated using the mask in the dark as easy or very easy.¹⁴⁻¹⁶
- Motivation to continue: 91% of the participants felt motivated to continue PAP therapy after using the F&P Nova Nasal mask.¹⁷
- Cleaning: 93% of the participants rated their ability to clean the mask as easy or very easy.¹⁸
- Minimal facial marks: 93% of the participants said the mask rarely or never left lingering visible marks on their face.¹⁹

The F&P Nova Nasal ensures a sound sleep, not just for the patient.

- Patient reported noise: 100% of the participants rated the noise level while sleeping as quiet or very quiet.²⁰
- Partner reported air draft: 85% of the participants' bed partners said the air draft rarely or never disrupted their sleep.²¹
- Partner-reported sleep quality: 75% of the bed partners rated their sleep quality as good or very good while the participant was using the F&P Nova Nasal mask.²²
- Air-flow diffusion: 93% of the participants rated the performance of the diffuser as good or very good.²³



Discussion

Establishing the Formation of PAP Use Patterns

A patient's experience with PAP therapy during the first nights following treatment initiation establishes behavioral trajectories that have been shown to forecast long-term PAP therapy use patterns. The initial setup of and adjustment period to PAP therapy therefore represents an intervention window where the patient's mask becomes a key factor as to whether this type of therapy becomes embedded as a nightly habit or begins to decline.¹ Within this period, elements of mask discomfort – such as instability or leak with positional change, noise or air draft and visual intrusion – can disrupt therapy acclimation and can predispose patients to discontinue PAP therapy.^{3,24} Masks that minimize the amount of contact with a patient's face, simplify the mask fitting and removal process, remain stable during movement and reduce sensory disturbance can all help to support the behavioral patterns associated with sustained PAP therapy use. In consideration of these factors, the F&P Nova Nasal demonstrated a performance profile reflective of design features that support successful PAP therapy, including patients already established on treatment. High ratings from participants in the clinical validation for comfort, ease of use and seal stability, combined with feedback demonstrating minimal noise and air draft, align directly with the sensory and usability attributes most strongly associated with positive long-term PAP therapy adherence trajectories.⁴

Translating Mask Design into Long-Term Therapy Use

Participants in the clinical validation consistently rated the key features of the F&P Nova Nasal as exceptionally high, including comfort (95%), stability (91%), seal performance (86%) and quietness (100%).^{7,8,10,20} These positive ratings are also strengthened by the 98% of participants who were able to sleep in their preferred position.⁹ In the context of PAP therapy, patient reported perceptions of comfort, stability, and sleep disruption are closely linked to whether therapy feels compatible with everyday life rather than as a treatment burden.^{3,24} Observational patterns of mask use further suggest that practical design plays an important role in supporting routine therapy use. The SwingFit headgear, which simplified setup and reduced the need for readjustment, was rated as intuitive or very intuitive by 91% of the participants. This was further confirmed by 98% of the participants rating mask removal as easy or very easy and 81% reporting the mask as easy or very easy to use in the dark.¹⁴⁻¹⁶ Noise and air draft can shape the sensory experience of receiving therapy during sleep. The F&P Nova Nasal mask reduces sensory disturbances commonly associated with therapy intolerance with 93% of the participants rating air-flow diffusion as good or very good and 100% reporting the mask as quiet while sleeping.^{20,23} Taken together, these findings indicate not only high satisfaction with individual features but also a cohesive mask experience that supports effective and stable PAP therapy use.

Nasal First, Not Nasal Only: Where F&P Nova Nasal Fits Within Mask Choice

Beyond the results of this clinical validation, evidence from meta-analyses highlights that mask selection meaningfully influences therapeutic pressure requirements, residual AHI and adherence outcomes.⁶ Across populations, nasal masks are frequently associated with lower therapeutic pressures and reduced residual AHI, reflecting physiological and interface related factors that may support effective therapy in appropriately selected patients.⁶ However, mask selection remains highly individual; optimal PAP therapy success depends on aligning mask design with patient specific needs, preferences, and clinical context. Within this framework, the F&P Nova Nasal clinical validation demonstrated strong seal performance (86%), stability across sleeping positions (98%), a clear field of view (84%) and nasal bridge comfort (98%). In combination, these qualities support an over-the-nose design that provides secure therapy delivery without increasing the facial contact area.^{7,9,13,25} An over-the-nose design provides a practical option for patients who struggle with pressure sensitivity, leak related arousals, or mask obtrusiveness when a nasal interface is clinically appropriate. Consistent with this, 91% of the participants reported feeling motivated to continue PAP therapy while using the F&P Nova Nasal.¹⁷ This is an important finding given that motivation mediates the relationship between early experience of and long-term adherence to PAP therapy.^{2, 24}

Partner Experience: A Factor of Sustained Use

PAP therapy is often used within a shared environment, so it is not shaped by the patient alone. Partner perceptions, particularly around noise, leak, air draft and sleep disruption, can directly influence the treatment experience for the patient.²⁶ Partner feedback reflected a favorable shared-sleep experience when the F&P Nova Nasal was used. Bed partners most often described nights with the mask being used as quiet, with 70% of the participants' bed partners rating the noise level as quiet or very quiet.²⁷ This reduces bedtime disruption and ensures it is easier for individuals to keep the same sleep-wake schedule. Also, 85% of the bed partners reported that air draft rarely or never disturbed their sleep; this means fewer interruptions to their sleep and better overall sleep quality, both of which can strain shared sleep routines when experienced.²¹ This was confirmed by 75% of the bed partners rating their own sleep quality as good or very good when the F&P Nova Nasal was used, an outcome that maintains a more supportive home environment for PAP therapy to continue.²² Taken together, consistent impressions from both participant and bed partners point to diffused noise as an effective means of reducing disruptive noise and noticeable air draft within the shared-sleep environment. All the participants rated the mask as quiet or very quiet during sleep (100%) and air-flow diffusion as good or very good (98%), reflecting bed-partner reports of minimal disturbance from noise and air draft.^{20,23} Overall, the results indicate that the F&P Nova Nasal not only helps the patient sleep more comfortably but also reduces common bed-partner irritants (noise and air draft) that can otherwise lead to negative attitudes towards PAP and pressure to discontinue therapy. By reducing the "social side effects" of PAP therapy, such design considerations sustain a more supportive sleep environment and promote long term use patterns.²⁶

Additional Features - Usability at the Center

Supportive features like a removable tube clip, structured side arms, and the AirEdge fabric of the F&P Nova Nasal are designed to reduce interaction burden and minimize unnecessary steps within a patient's sleep routine. The considerations were informed by common disruptions, such as tugging tubes, twisted straps and overtightened headgear, which frequently prompt night-time adjustments and can disrupt sleep continuity and increase the likelihood of leaks and arousals. The removable tube clip is designed to give patients flexibility in tube positioning, allowing them to route the tubing over their head or leave it free hanging based on individual preference and sleep behavior. By enabling patients to experience and select the configuration that best suits their routine, tube tension can be managed in a way that minimizes pulling on the mask and twisting or shifting at the seal when patients turn in bed. This approach supports a more personalised setup without committing patients to a single routing solution. The structured side arms provide a defined, twist resistant profile that reduces strap tangling and helps maintain easier headgear configuration during low light setup. Paired with SwingFit for intuitive adjustment (91%), the headgear of the F&P Nova Nasal supports positional stability without adding bulk.¹⁴ The integrated AirEdge fabric provides softer contact between the headgear and skin, reducing the potential for visible marks, which was confirmed by 93% of the participants reporting that the F&P Nova Nasal rarely or never left lingering visible marks on their face.¹⁹ For clinicians, these design details offer practical opportunities during setup and education to discuss tube management options, avoid overtightening and reduce the need for readjustments. Together, these features help establish a positive experience and support seamless integration of PAP therapy into individualized patients' sleep routines.

Care by Design™, Night by Night

For patients, PAP therapy use is lifelong, and periods of equipment renewal, potential change to weight, nasal symptoms or bed-partner concerns can unsettle previously well-established therapy habits. Mask choice remains clinically meaningful beyond initiation: it influences noise, air draft, facial contact, seal stability and the number of micro-interactions required to take on and off the mask as well as readjust. The validation results of the F&P Nova Nasal mask report a low disturbance and easy-to-use mask that supports continuing with PAP therapy. Patient reported outcomes align with fewer readjustments and sensory disruptions, conditions which can promote or undermine long term therapy use. A shared-sleep environment with the F&P Nova Nasal was favorable as well, with bed partners rating the noise level and reported air draft as quiet and undisruptive, outcomes that help sustain supportive home environments over time. These findings reflect F&P's Care by Design ethos, which is to reduce burden, simplify routine and create products that integrate naturally into real world sleep environments. By centering patient and bed-partner needs - including low contact, stability, quietness and ease of use - into the design, the F&P Nova Nasal supports both early success and long term continuation, strengthening the path towards sustainable PAP therapy.



Figure 4. F&P Nova Nasal

References

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7. 37 out of 43 users rated the overall seal performance of the F&P Nova Nasal mask as “good” or “very good”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
8. 39 out of 43 users rated the overall stability of the F&P Nova Nasal mask as “stable” or “very stable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
9. 42 out of 43 users were “often” or “always” able to sleep in their preferred sleeping position while wearing the F&P Nova Nasal mask. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
10. 41 out of 43 users rated the overall comfort of the F&P Nova Nasal mask as “comfortable” or “very comfortable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
11. 41 out of 43 users rated the comfort of the headgear on the F&P Nova Nasal mask as “comfortable” or “very comfortable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
12. 40 out of 43 users rated the comfort of the cushion on the F&P Nova Nasal mask as “comfortable” or “very comfortable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
13. 36 out of 43 users rated their field of view while wearing the F&P Nova Nasal mask as “clear” or “very clear”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
14. 39 out of 43 users rated the process of putting on the F&P Nova Nasal mask using SwingFit as “intuitive” or “very intuitive”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
15. 42 out of 43 users rated taking off the F&P Nova Nasal mask as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
16. 35 out of 43 users rated using the F&P Nova Nasal mask in the dark as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
17. 39 out of 43 users agreed or strongly agreed with the following statement: “After using the F&P Nova Nasal mask, I feel motivated to continue PAP therapy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
18. 40 out of 43 users rated their ability to clean the F&P Nova Nasal mask as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
19. 40 out of 43 users said the F&P Nova Nasal mask “rarely” or “never” left lingering visible marks on their face. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
20. 43 out of 43 users rated the noise level of the F&P Nova Nasal mask while sleeping as “quiet” or “very quiet”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
21. 17 out of 20 partners of F&P Nova Nasal mask users said the air draft “rarely” or “never” disrupted their sleep. Internal validation trial conducted by Fisher & Paykel Healthcare on 20 bed-partners of F&P Nova Nasal mask users in the United States, 2023.
22. 15 out of 20 partners of F&P Nova Nasal mask users rated their sleep quality as “good” or “very good” while their partner was wearing the mask. Internal validation trial conducted by Fisher & Paykel Healthcare on 20 bed-partners of F&P Nova Nasal mask users in the United States, 2023.

23. 40 out of 43 users rated the performance of the diffuser on the F&P Nova Nasal mask as “good” or “very good”. Internal validation trial conducted by Fisher & Paykel Healthcare on 43 participants in the United States, 2023.
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26. Gentina T, Bailly S, Jounieaux F, Verkindre C, Broussier PM, Guffroy D, et al. Marital quality, partner’s engagement and continuous positive airway pressure adherence in obstructive sleep apnea. *Sleep Med*. 2019 Mar 1;55:56–61.
27. 14 out of 20 partners of F&P Nova Nasal mask users rated the noise level as “quiet” or “very quiet”. Internal validation trial conducted by Fisher & Paykel Healthcare on 20 bed-partners of F&P Nova Nasal mask users in the United States, 2023.