Mask Matters Most - Evora Nasal

Fisher & Paykel Healthcare (F&P)



Background

PAP therapy, which consists of pressurized air applied to the airway via a mask, is the most widely used treatment for obstructive sleep apnea (OSA).¹ However, adherence to PAP therapy is a significant problem, with adherence rates ranging from 30–60%.^{1,2} The mask component of PAP therapy is what patients interact most closely with, its function being to form a sealed connection from the PAP machine blower to the patients airways via either the nose, mouth or both. To enable patients to have a positive experience with PAP therapy, F&P uses a Mask Matters Most design philosophy. The F&P Evora Nasal is a new compact sub-nasal mask that has been designed with OSA patients' fit and usability, comfort and lifestyle needs in mind. The purpose of this report is two-fold: first, to outline the effect of the mask on PAP therapy adherence, and secondly to demonstrate how F&P designed the Evora Nasal with the Mask Matters Most design philosophy.

Fit and usability

OSA patients initial experiences with PAP therapy can impact adherence.^{3,4} Research examining initial mask acceptance rates found that patients who switched their mask had a seven-fold higher risk of abandoning PAP therapy.³ Moreover, Scharf et al., found a clear linear relationship between the number of mask refits and PAP therapy adherence; if a patient had a mask refit, their PAP usage was lower by 1.3 hours/day over the first 90 days of treatment.⁴ Therefore, to avoid mask switching and refits, F&P strives to create masks that are simple to fit and use.

The intuitive design of the Evora Nasal resulted in strong results in an internal clinical trial, with fitting and removal of the mask rated as simple by 95% and 93% of sleep technicians and participants, respectively.⁵ Furthermore, the CapFit headgear design was well received; 93% of participants thought that fitting of the Evora Nasal was similar to putting on a baseball cap and 98% of participants found the Evora Nasal simple to put on and take off in the dark.⁵ Through simplifying the fitting process and improving mask usability, the Evora Nasal may encourage daily PAP use.

Comfort

Mask comfort significantly influences PAP therapy adherence.³ A study by Riachy et al. showed that nearly half of all participants experienced mask discomfort, and side-effects related to the mask were the most common reason for stopping PAP therapy.⁶ Similarly, Weaver and Grunstein (2008) concluded that non-adherence to PAP therapy was caused by mask-related side-effects including claustrophobia, leak, and facial imprinting.³ Therefore, comfort is a key consideration when designing masks at F&P.

The Evora Nasal features the next generation of dynamic support; the floating seal allows greater freedom of movement, while the stability wings and headgear provide support. Results from an internal F&P clinical trial demonstrated that 76% and 80% of participants rated the Evora Nasal seal and headgear as comfortable/very comfortable, respectively.⁵ Claustrophobia is known to be a significant concern for PAP users, and a common cause of nonadherence.³ The Evora Nasal helps overcome this issue with its compact sub-nasal profile.

Lifestyle

The intrusive nature of PAP therapy requires a dramatic lifestyle change. PAP therapy can disrupt patients' normal bedtime and sleep routines. Additionally, PAP therapy can negatively affect patients' partners' sleep and their willingness to support patient PAP use.⁷ Therefore, it is evident that PAP therapy integration into not only the patients but also their partners lifestyles is paramount.

Lifestyle factors were considered when designing the Evora Nasal. Results from an internal F&P clinical trial suggest that users can perform their normal bedtime routines (e.g., reading) with the Evora Nasal as 86% of participants reported that their vision was unobstructed whilst wearing the mask.⁵ A total of 70% of participants also found they could sleep in their preferred sleep position with the Evora Nasal.⁵ The Evora Nasal was also well received by participants partners as noise and draft did not disturb sleep in 77% and 86% of participants partners, respectively.⁵ By reducing the disruption to both patients and partners bedtime routines and sleep, the Evora Nasal mask may help integrate PAP therapy into patients lifestyles and aid adherence.

Mask Matters Most design philosophy

The primary goal at F&P is to improve care and outcomes for patients. To achieve this, F&P dedicates hours of time researching, engineering, and conducting clinical trials before releasing PAP therapy masks into the market. The Mask Matters Most design philosophy was used for the Evora Nasal, and the success of this philosophy was evidenced by the positive internal clinical trials results for fitting and usability, comfort, and lifestyle integration.⁵ With our strong belief in why the Mask Matters Most, F&P is continuing to make strides towards meeting the expectations of patients and healthcare professionals with our range of innovative masks.

References

1.

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