

# The Mask Matters Most – F&P Evora Nasal

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## Background

Despite the well-recognized health benefits of positive airway pressure (PAP) therapy for managing obstructive sleep apnea (OSA), non-adherence and inconsistent use still pose a significant barrier to effective treatment.<sup>1</sup> PAP therapy is currently among the most effective and widely prescribed treatment options for OSA.<sup>2</sup> It involves the delivery of pressurized air to the upper airway to prevent it from repeated full or partial collapse throughout the night. This decreases the number of arousals a patient experiences during sleep.<sup>3,4</sup> Long-term use of PAP therapy is associated with many health benefits, including improving sleep quality and overall quality of life.<sup>5</sup> Untreated OSA can be a risk factor for cardiovascular disease, leading to complications such as hypertension and type 2 diabetes mellitus.<sup>6</sup> In addition, daytime fatigue can lead to an increased risk of accidents.<sup>7</sup> Although there have been various technological advancements to PAP therapy devices and masks in recent years, too many patients are discontinuing treatment. Poor adherence can lead to higher rates of OSA-linked complications, if OSA is left untreated. The most widely used criterion for mask adherence is usage of PAP for more than four hours per night, for at least 70% of nights.<sup>8</sup> However, studies have shown that up to 15% of patients refuse PAP therapy after the first night and more than 50% discontinue treatment within the first year of beginning therapy.<sup>9,10</sup> Common contributors to PAP therapy non-adherence include claustrophobia or anxiety from wearing a mask, unattractive or complex mask headgear, and side effects such as facial imprinting, unintentional leak, and noise.<sup>11,12</sup> Not only is increasing long-term adherence essential, but consistent nightly use of PAP therapy is equally as important. Studies have demonstrated that excessive daytime sleepiness and poor concentration caused by untreated OSA arise or reappear even with the withdrawal of PAP for one night.<sup>13</sup> Any use of PAP therapy is better than no use in patients

with OSA. However, clinically significant improvements in OSA outcomes can only be obtained with more extended and consistent nightly use, usually achieved with six or more hours of sleep per night.<sup>12,14</sup>

The mask component of the PAP therapy system is what patients interact most intimately with, but among the most common complaints relating to poor compliance is mask-related side effects.<sup>15</sup> Accordingly, appropriate mask selection is the primary determinant of treatment adherence and efficacy.<sup>16</sup> The current research landscape for OSA treatment primarily focuses on improving mask design and usability in order to increase ongoing PAP therapy compliance. The use of nasal masks over a full-face option is generally associated with greater treatment compliance. This is also reflected in clinical practice, where the first choice of mask for a patient is usually a nasal or nasal pillows mask.<sup>11,17</sup> Evidence suggests that nasal masks can help reduce mouth opening and the number of oral breaths during sleep. For this reason, nasal masks are also recommended for mouth breathers.<sup>18</sup> Research suggests that the best mask is the one a patient will wear.<sup>19</sup> Therefore, overcoming problems related to mask fitting and stability, discomfort, unintentional leak, and claustrophobia are critical to improving long-term adherence.<sup>19</sup> It is always important to involve the patient during the initial mask selection. The Fisher & Paykel Healthcare (F&P) Evora™ Nasal is the newest F&P nasal mask. It features a compact nasal profile, CapFit™ headgear, and the next generation of Dynamic Support Technology™. Evora Nasal was designed to provide effective PAP therapy while ensuring comfort and ease of use, with the intention of improving long-term treatment adherence among users.



## Simplicity and ease of use

Patients with OSA may experience some difficulty while putting on, taking off, and using a PAP therapy mask.<sup>20</sup> Those with poor health literacy or restricted body movement may be further discouraged or intimidated by having to use a mask. Therefore, it is important to offer patients mask options that are simple to use. A study by Ellender et al. found that OSA patients with inadequate health literacy are at a more than two-fold increased risk of inadequate PAP therapy usage.<sup>21</sup> Martinez-Garcia et al. demonstrate that adherence significantly declines in the elderly population.<sup>22</sup> Evora Nasal excels in its simplicity of use. Unlike any other mask, the Evora Nasal features the F&P streamlined CapFit headgear which allows patients to intuitively put the mask on like a cap. Results from an internal validation trial confirmed this, with 93% of participants reporting that the mask-fitting process was similar to putting on a baseball cap.<sup>23</sup> The Evora Nasal also performed strongly in regard to simplicity of use, with 93% of participants rating the fitting process as “very simple” and 95% rating removal of the mask as “simple”.<sup>24,25</sup> Additionally, this straightforward and familiar fitting technique resulted in 98% of participants finding the Evora Nasal “simple” to put on and take off in the dark.<sup>26</sup>

PAP therapy can be intrusive in nature, disrupting the lifestyle of both patients with OSA and their partners. A study by Bachour et al. found most patients consider the use of a PAP therapy mask disturbing. This is even when the satisfaction rate is good, with no differences in experience between brands of masks used.<sup>27</sup> F&P’s Care by Design™ approach to developing masks ensures that lifestyle factors, including bedtime routine and preferred sleeping position, are considered during the design process. In particular, the sub-nasal design of the Evora Nasal is unobstructive, with 86% of participants enrolled in the internal validation trial agreeing that their vision was “completely unobstructed” or “unobstructed” while wearing the mask.<sup>28</sup> Having a clear field of view enables patients to continue with bedtime activities, such as wearing glasses to read. Many patients using PAP therapy also report feelings of claustrophobia or anxiety while wearing a mask. This may create a psychological barrier to consistent use.<sup>29</sup> Evora Nasal has a compact nasal profile and minimal contact on the face, and may help overcome the issue of claustrophobia experienced during PAP therapy. Mask desensitization is recommended for claustrophobic patients to improve their adherence.<sup>29</sup> This may involve wearing the mask at moments throughout the day to increase tolerance. Claustrophobic patients using PAP therapy for more than five hours a night have been shown to exhibit fewer claustrophobic tendencies than those using PAP for shorter periods.<sup>12</sup> Evora Nasal helps combat these issues as it can easily be incorporated into a patient’s lifestyle, with a high comfort and an unobtrusive design, intended to promote adherence and consistent use in patients with anxiety or psychological barriers to treatment.

## Comfort and stability

Mask comfort significantly determines a patient’s adherence and usage of PAP therapy.<sup>29</sup> A comfortable mask is one that generates the least amount of disturbance to a patient. All patients have individualized qualities and behaviors, for example, their sleep habits, facial profiles, and breathing patterns, that should be accounted for in mask design. F&P aims to simplify the fitting process and provide patients with a suitable and appropriately-sized mask during their first consultation. A study by Riachy et al. demonstrated that while 82% of patients reported an improvement in OSA severity following PAP treatment, nearly half, or 48%, experienced some level of discomfort.<sup>30</sup> A study by Bachour et al. found that, among patients with OSA who switched masks, poor fit, mask discomfort, and leak issues were reported in more than two-thirds of cases.<sup>31</sup> The Evora Nasal headgear is manufactured with soft-knit fabric designed to avoid leaving marks on the face. Together with the next generation of F&P’s Dynamic Support Technology, which incorporates stability wings and a soft, floating seal that sits discreetly under the nose, Evora Nasal can provide the stability necessary for sleeping in multiple positions comfortably. The internal validation trial with Evora Nasal found that in addition to successfully delivering effective treatment for OSA, participants were also highly satisfied with the comfort of the mask. A “very comfortable” and “comfortable” score for the Evora Nasal seal and headgear was reported in 76% and 80% of participants, respectively.<sup>32,33</sup> In participants with previous experience using sub-nasal masks, the majority of users did not report any issues with stability.<sup>34</sup> Collectively, these results demonstrate that the Evora Nasal is a comfortable mask, which may help promote PAP therapy adherence in new and experienced mask users.

## The Mask Matters Most design philosophy

Long-term PAP therapy use patterns are most commonly established in the first few days of beginning treatment.<sup>35</sup> Among patients who are new to PAP therapy, about 19% switch their masks during the first year of treatment, although most switches occur in the first two weeks.<sup>1</sup> The Bachour et al. study also found that patients who switched masks were seven times more likely to stop PAP therapy within one year when compared with patients who did not switch masks.<sup>31</sup> The evidence presented in this report emphasizes the importance of ensuring a successful early experience with PAP therapy for OSA patients, and that PAP therapy success significantly depends on the selection of the proper mask during treatment initiation. At F&P, our masks are carefully designed and developed with performance, simplicity of use, and patient comfort in mind. Following The Mask Matters Most™ philosophy, F&P has released award-winning masks to the global market that have exceeded efficacy and usability expectations among patients and healthcare professionals. With our strong belief in why the ‘mask matters most’, F&P is continuing to make strides towards meeting the needs of patients with our range of innovative masks and mask technologies.

## References

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24. 41 of 44 participants rated the F&P Evora Nasal CapFit headgear as "very simple" or "simple" to assist in wearing the mask. Internal validation trial conducted by Fisher & Paykel Healthcare with 45 participants in the United States. 2019.
25. 42 of 44 participants rated the F&P Evora Nasal CapFit headgear as "very simple" or "simple" to assist in taking off the mask. Internal validation trial conducted by Fisher & Paykel Healthcare with 45 participants in the United States. 2019.
26. 43 of 44 participants were able to don and doff the F&P Evora Nasal once fitted or adjusted in the dark. Internal validation trial conducted by Fisher & Paykel Healthcare with 45 participants in the United States. 2019.
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33. 38 of 44 participants rated the comfort of the F&P Evora Nasal seal under the nose as "very comfortable", "comfortable", or "average". Internal validation trial conducted by Fisher & Paykel Healthcare with 45 participants in the United States. 2019.
34. 9 of the 11 previously sub-nasal mask users rated the F&P Evora Nasal as "very stable", "stable", or "neither stable or unstable". Internal validation trial conducted by Fisher & Paykel Healthcare with 45 participants in the United States. 2019.
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