

F&P Evora Full - Prepared by Fisher & Paykel Healthcare



of respondents rated seal performance as very good or good¹



of respondents never or rarely experienced leak into their eyes²



of respondents found the mask very comfortable or comfortable³

*Performance outcomes for the Evora Full™ mask collected from participants during clinical investigation.

Abstract

This whitepaper outlines the details of a Fisher & Paykel Healthcare (F&P) sponsored clinical investigation that assessed the performance and comfort of the new F&P Evora Full mask among experienced full-face mask positive airway pressure (PAP) therapy users (n=44). The participant cohort used PAP therapy primarily for the treatment of obstructive sleep apnea (OSA). The Evora Full is a compact full-face mask featuring the next generation of Dynamic Support Technology™ that was designed to optimize performance and comfort throughout the night. The results from this investigation demonstrate that the Evora Full is a high-performing mask, particularly with regards to its ability to seal on the face, reduce unintentional leak into the eyes, and enhance the overall comfort of receiving PAP therapy. These results make the Evora Full a strong player in the compact full-face mask category for PAP therapy, and means that it is a particularly good option for those who are mouth breathers, but are at risk of experiencing claustrophobia, or for those that like to read or acclimatize to PAP therapy before going to sleep.

1.0 Introduction

PAP therapy, which consists of pressurized air applied to the airway via a mask, is commonly used in the context of chronic medical care to assist in airway management for several respiratory conditions, including OSA and obesity hypoventilation syndrome (OHS).⁴ There are many masks on the market for use with PAP therapy devices. A comfortable and appropriate fitting mask that minimizes the impact of leak is essential to the users' tolerance to and acceptance of PAP therapy.⁵ Full-face masks are used as part of the PAP therapy system, most commonly by those who are unable to use nasal masks due to excessive mouth leak (i.e., mouth breathing).⁶ However, traditional over-the-nose full-face masks are associated with several disadvantages (e.g., increased dead space resulting in greater work of breathing, nasal bridge discomfort, and claustrophobia) that may reduce users' adherence to PAP therapy.⁵ Increasing compliance with PAP therapy is crucial, given it is the main barrier to achieving long-term effective treatment among users.⁷

As a result of these well-documented challenges, F&P has developed a new compact full-face mask, the Evora Full shown in Figures 1, 2, and 3. This mask was designed to mitigate the shortcomings associated with traditional over-the-nose full-face masks. The Evora Full, featuring unique Dynamic Support Technology, has the following key features:

- The Evora Full is a compact mask that seals under the nose and provides users with a clear line of sight.
- The Evora Full has a floating seal that works in conjunction with the stability wings.



Figure 1, 2 & 3. The Evora Full mask featuring the next generation of Dynamic Support Technology that includes a floating seal and stability wings

The aim of this clinical investigation was to evaluate the performance and comfort of the Evora Full mask in a home environment among existing full-face mask users who have been prescribed PAP therapy by a physician.

2.0 Methods

2.1 Participant Selection

All participants were screened during the recruitment process according to the criteria below:

The inclusion criteria for this investigation was:

- aged ≥ 22 years
- weighed ≥ 66 lbs (approximately 30 kgs)
- prescribed PAP (APAP, BPAP or CPAP) therapy by a physician
- compliant PAP therapy user for ≥ 4 hours per night for 70% of nights for at least two weeks prior to enrolment in the investigation
- currently using a full-face mask
- persons who have an IPAP pressure of < 30 cmH₂O
- persons who have a PAP therapy device with data-recording capabilities
- fluent in written and spoken English
- capacity to provide informed consent.

The exclusion criteria for this investigation was:

- inability to provide informed consent
- intolerant to PAP therapy
- required PAP therapy for more than 12 hours per day or for extensive periods other than sleep or naps
- currently using nasal or nasal pillows masks
- anatomical or physiological conditions that make PAP therapy inappropriate
- participant is pregnant or think they may be pregnant
- PAP therapy device used for delivery of medicines (excluding oxygen)
- cold or flu-like symptoms at the time of recruitment
- tested positive for COVID-19 within 28 days prior to enrolment.

2.2 Study Design Currently

A prospective, non-randomized study design was used in this clinical investigation. This investigation was funded and sponsored by F&P and took place across three investigation sites in New Zealand: Hawke's Bay

District Health Board (HBDHB), a hospital in Hastings; WellSleep, a sleep clinic in Wellington; and the F&P sleep laboratory in Auckland. Figure 4 shows the investigation timeline. The investigation required that participants attend two appointments at the investigation site where they were enrolled. During the first visit, informed consent was obtained prior to any procedures being completed. Subsequently, participant demographic data was recorded and a retrospective download of the participants' baseline compliance data from their usual PAP therapy device was generated. The Evora Full was then appropriately fitted by a mask-fitting expert (e.g., sleep technician, nurse, or qualified healthcare professional) and issued. Participants' initial feedback was gathered via a questionnaire. Participants were then asked to use the Evora Full for two weeks at home, and they were issued a sleep diary to keep track of their daily progress with the Evora Full. A follow-up phone call or email was made three days (plus or minus two days) after the first visit and the participants' feedback, including any side effects or adverse events, was recorded. The second visit took place 14 days after the first visit, during which compliance data, including Apnea-Hypopnea Index (AHI) and leak, was downloaded and feedback was collected via a participant interview and questionnaire. The Evora Full was then returned, and the investigation was complete.

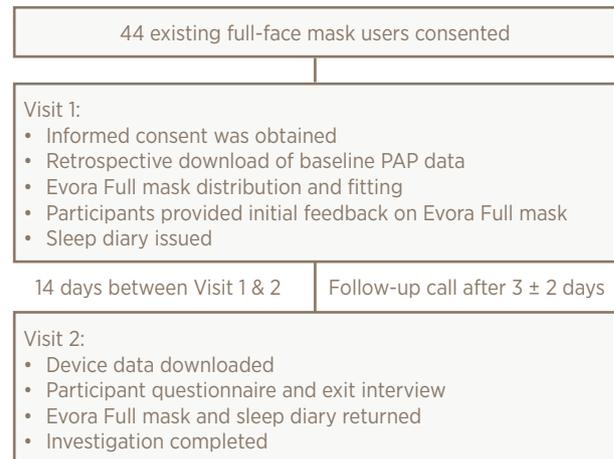


Figure 4. Timeline for the Evora Full clinical investigation.

2.3 Outcome Measures

2.3.1 Mask Performance

This investigation assessed the following measurements:

- Participants' rating of the Evora Full for mask performance, including:
 - Overall seal performance – participants selected an answer from the options 'very good', 'good', 'poor' or 'very poor' for the question, 'How do you rate the overall seal performance of the Evora Full mask on your face?'
 - Stability of the mask – participants selected an answer from the options 'very stable', 'stable', 'unstable' or 'very unstable' for the question, 'How do you rate the stability of the Evora Full mask?'

- Unintentional leak – participants selected an answer from the options ‘never’, ‘rarely’, ‘often’ or ‘always’ for the question, ‘How often did you experience unintentional air leak into your eyes when sleeping with the Evora Full mask?’

2.3.2 Mask Comfort

- Participants’ rating of the Evora Full for mask comfort, including:
 - Overall comfort – participants selected an answer from the options ‘very comfortable’, ‘comfortable’, ‘uncomfortable’ or ‘very uncomfortable’ for the question, ‘How do you breakdown by location the overall comfort of the Evora Full mask?’
 - Feel of the seal under the nose – participants selected an answer from the options ‘very soft’, ‘soft’, ‘hard’ or ‘very hard’ for the question, ‘How does the Evora Full mask seal feel on your skin?’
 - Comfort of seal under nose – participants selected an answer from the options ‘very comfortable’, ‘comfortable’, ‘uncomfortable’ or ‘very uncomfortable’ for the question, ‘How comfortable was the feel of the Evora Full mask seal under your nose?’
 - Claustrophobia – participants selected an answer from the options ‘never’, ‘rarely’, ‘often’ or ‘always’ for the question, ‘At any time, did you feel claustrophobic while wearing the Evora Full mask?’
 - Freedom of movement – participants selected an answer from the options ‘very easy’, ‘easy’, ‘difficult’ or ‘very difficult’ for the question, ‘How easy was it to move around in bed while wearing the Evora Full mask?’

3.0 Results

3.1 Participant Demographics

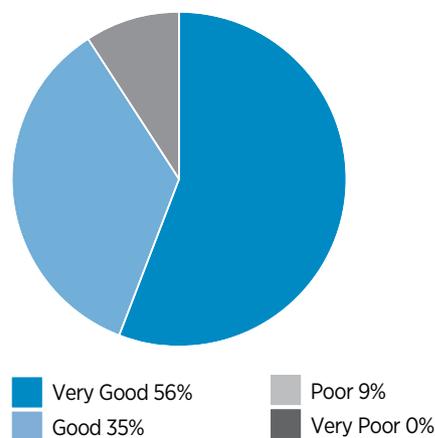
Forty-four participants completed the two-week, in-home investigation with the Evora Full. The sample population breakdown by location was HBDHB (32%), WellSleep (43%), and F&P (25%). The age range of participants was 22-39 years (4.6%), 40-59 years (44.2%) and 60 years or older (51.2%). The duration participants had been receiving PAP therapy was less than a year (41%), between 1-6 years (41%) or more than 6 years (18%). To represent the PAP therapy population, BPAP users (9%), participants of non-European descent (16%) and female participants (27%) were included in this clinical investigation. There were no participant withdrawals during this investigation.

3.2 Evora Full Performance

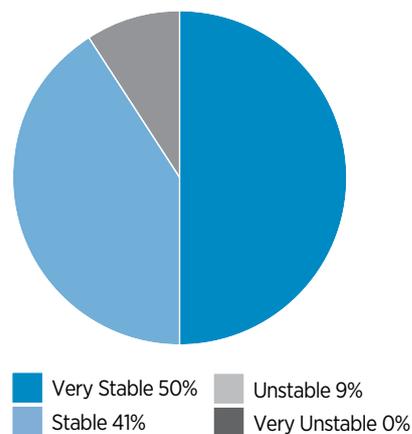
The Evora Full is a high-performing mask. In this investigation, participants who used the Evora Full for the entire duration of the investigation period had low levels of leak and demonstrated maintenance of their AHI within an acceptable range, in comparison to data from

their baseline compliance reports. The Evora Full stability wings were designed to optimize seal performance and keep the mask in place throughout the night. In this investigation, 91% of participants rated the overall Evora Full seal performance as “very good” or “good” (Figure 5A).¹ Furthermore, 91% of participants rated the stability (i.e., mask staying in place on the face while sleeping) of the Evora Full as “very stable” or “stable” (Figure 5B).⁸ In line with these high ratings for seal performance and stability, 93% of participants “never” or “rarely” experienced unintentional air leak into their eyes (Figure 5C).² Finally, 96% of participants reported it was “very easy” or “easy” to move around in bed while wearing the Evora Full (Figure 5D).¹³ Overall, the Evora Full’s compact design, stable fit, and floating seal harmoniously work together to support freedom of movement in bed and stability while wearing the mask.¹³

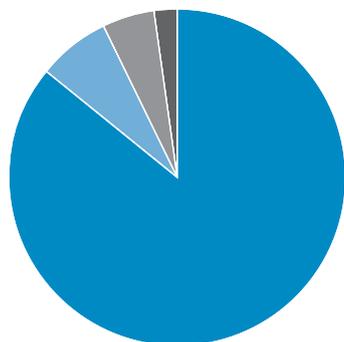
5A Seal performance



5B Mask stability

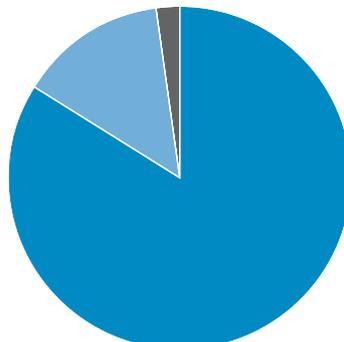


5C Mask leak into eyes



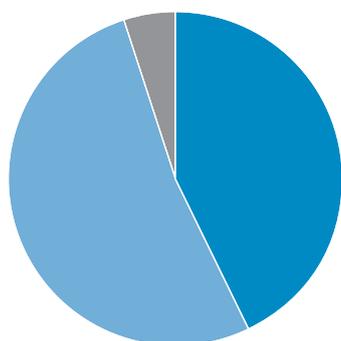
Never 86%
Rarely 7%
Often 5%
Always 2%

6A Feeling of claustrophobia



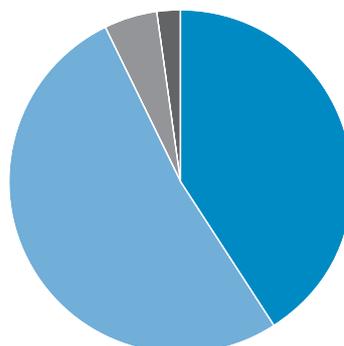
Never 84%
Rarely 14%
Often 0%
Always 2%

5D Freedom of movement in bed



Very Easy 43%
Easy 52%
Difficult 5%
Very Difficult 0%

6B Overall comfort



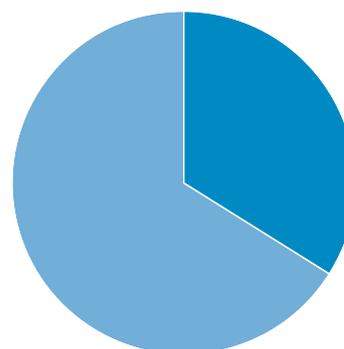
Very Comfortable 41%
Comfortable 52%
Uncomfortable 5%
Very Uncomfortable 2%

Figure 5. Performance outcomes of the F&P Evora Full mask: (A) Seal performance; (B) Mask stability; (C) Mask leak into eyes; (D) Freedom of movement in bed.

3.3 Evora Full Comfort

A key feature of the Evora Full is the compactness of the mask. Almost all participants thought the Evora Full was compact,¹¹ and 98% reporting “never” or “rarely” experiencing claustrophobia while using the mask (Figure 6A).¹² Participants showed a high level of satisfaction with the Evora Full, rating comfort highly across all features. A total 93% of participants rated the overall comfort of the Evora Full as “very comfortable” or “comfortable”.³ More specifically, the Evora Full under-the-nose seal was well received by participants in terms of comfort and feel - 93% rated the Evora Full under-the-nose seal as comfortable (Figure 6B)⁹ and 100% found that the Evora Full seal was “very soft” or “soft” on their skin (Figure 6C).¹⁰

6C Mask feel on skin



Very Soft 34%
Soft 66%
Hard 0%
Very Hard 0%

Figure 6. Comfort outcomes of the F&P Evora Full mask: (A) Feeling of claustrophobia; (B) Overall comfort; (C) Mask feel on skin.

4.0 Discussion

Compliance with PAP therapy is the primary predictor of treatment efficacy. Mask discomfort, unintentional leak, and claustrophobia are common reasons for non-adherence.^{15,16} As many as 50% of users may also experience local side effects, such as pressure sores or skin ulceration due to poor mask fit. They may constantly replace or switch between different masks to reduce or resolve these issues.¹⁷ Those who switch their mask, even on an infrequent basis, are more likely to prematurely abandon PAP therapy. Given that chronic conditions such as OSA are associated with considerable morbidity and mortality, it is imperative to promote adherence.¹⁸ This can be achieved by reducing unintentional leak or improving mask fit, and in particular, alleviating excess pressure on the skin.¹⁷ The Evora Full is a compact full-face mask featuring the next generation of Dynamic Support Technology, intended to enhance mask fit and improve the overall experience of receiving PAP therapy. Participants who used the Evora Full mask during the investigation provided high ratings for its overall seal performance, stability, and comfort. Following the investigation, the majority indicated they would use the Evora Full mask going forward.¹⁴

Claustrophobia a specific concern for those who wear a full-face mask for PAP therapy.¹⁵ The Evora Full features a unique under-the-nose seal, intended to make the mask feel more compact on the face compared to traditional over-the-nose full-face masks. In this investigation, 98% of participants found that the Evora Full was compact.¹¹ Results from this investigation also suggest that the Evora Full did not induce feelings of claustrophobia among most participants, with 98% “never” or “rarely” experiencing claustrophobia while wearing the mask.¹² The Evora Full also features a floating seal to allow greater flexibility and freedom of movement, while the stability wings provide structure and support. The benefits of this design feature were confirmed by 96% of participants who found it “easy” to move in bed while wearing the Evora Full.¹³

Abnormal mask leak is a common side effect of PAP therapy that can cause a cascade of issues, such as eye irritation, sleep disruption due to unwanted noise for the user or their bed partner, airway drying, and ineffective treatment due to a potential reduction in the pressure delivered to the upper airway.⁵ The Evora Full is comprised of stability wings and a floating seal, designed to keep the mask in place throughout the night despite movement in bed. These elements in combination have been shown to prevent unintentional mask leak, with 93% of participants in the investigation “never” or “rarely” experiencing leak into their eyes while using the Evora Full, and 91% of participants rated the overall Evora Full seal performance as “very good” or “good”.¹

Mask comfort, especially in relation to seal softness across the multiple contact points on the face, is a key

determinant of long-term PAP therapy adherence.¹⁷ The Evora Full was designed to account for the widespread issue of having excess pressure or stress on or against the skin for prolonged periods of time while wearing a mask. Results from this investigation demonstrate that the Evora Full is comfortable, in addition to offering strong performance capability. This was evidenced by feedback obtained through the investigation, with 93% of participants rating the Evora Full as “comfortable” or “very comfortable” overall.³ Furthermore, the majority had a positive experience with the Evora Full under-the-nose seal, rating it as “comfortable”⁹ and “soft” on their skin.¹⁰

There were several limitations associated with this clinical investigation. This was a non-blinded investigation. Therefore, potential bias from participants and investigators cannot be fully eliminated. In addition, the lack of crossover with a control or alternative mask may be considered a limitation because the data collected on Evora Full could not be compared against other mask types. Finally, this study was conducted with a sample of New Zealand participants only, which may limit the generalizability of findings to other populations. However, we are confident that the demographic variation, with regards to age, ethnicity, and gender, obtained as part of recruitment for this study, is representative of the wider global PAP therapy population.

5.0 Conclusion

The feedback from this in-home investigation confirms the Evora Full is a high-performing and comfortable mask that has the potential to improve users’ overall experience with PAP therapy. The compactness of the Evora Full means the mask is a great option for those who are mouth breathers requiring a seal over the nose and mouth, but are at risk of experiencing claustrophobia, or prefer to read or acclimatize to PAP therapy before going to sleep. Therefore, the Evora Full is a viable option for both naive users of PAP therapy and existing full-face mask users. The comfort and softness of the Evora Full seal was also rated highly across the participant cohort and may alleviate excess pressure on the skin. This makes it a suitable alternative for users who are prone to mask switching as a consequence of experiencing skin irritation or poor mask fit. Given the increasing utilization of PAP therapy globally, designing high-performing and comfortable masks, like the Evora Full, is paramount to improve the users’ adherence, experience, and overall response to PAP therapy.

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References

1. 39 out of 43 participants rated the overall seal performance of the Evora Full mask as “good” or “very good”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
2. 41 out of 44 participants experienced unintentional leak into their eyes while sleeping with the Evora Full mask “rarely” or “never”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
3. 41 out of 44 participants rated the overall comfort of the Evora Full mask as “comfortable” or “very comfortable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
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8. 40 out of 44 participants rated the overall stability of the Evora Full mask as “good” or “very good”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
9. 32 out of 44 participants rated the comfort of the Evora Full mask seal under their nose as “comfortable” or “very comfortable”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
10. 44 out of 44 participants rated the feel of the Evora Full mask seal on their skin as “soft” or “very soft”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
11. 43 out of 44 participants rated the overall size of the Evora Full as “compact”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
12. 43 out of 44 participants found the Evora Full mask “rarely” or “never felt” claustrophobic. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
13. 42 out of 44 participants rated the ease of movement in bed while wearing the Evora Full mask as “easy” or “very easy”. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
14. 29 out of 44 participants indicated that they would continue to use the Evora Full mask. Internal validation trial conducted by Fisher & Paykel Healthcare on 44 participants in New Zealand. 2020.
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