

Nasal mask for use in the home or hospital



| Mask Specifications | | |
|---------------------------------|---|--|
| Contraindications | None | |
| Operating pressure | 4 to 25 cmH ₂ O | |
| Resistance to flow through mask | Pressure drop through mask with small Seal at 50 L/min: 1.0±0.1 cmH ₂ O Pressure drop through mask with small Seal at 100 L/min: 1.4±0.25 cmH ₂ O. Pressure drop through mask with medium Seal at 50 L/min: 1.0±0.1 cmH ₂ O Pressure drop through mask with medium Seal at 100 L/min: 1.2±0.25 cmH ₂ O Pressure drop through mask with large Seal at 50 L/min: 1.0±0.1 cmH ₂ O Pressure drop through mask with large Seal at 100 L/min: 1.2±0.25 cmH ₂ O Pressure drop through mask with wide Seal at 50 L/min: 1.0±0.1 cmH ₂ O Pressure drop through mask with wide Seal at 100 L/min: 1.3±0.25 cmH ₂ O | |
| Interface connections | ISO 5356-1 Conical Connectors | |
| Quantity per box | 10 | |
| Intended use | To be used by adults weighing ≥ 66 lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or bilevel by a physician. | |
| Storage temperature | -20 to 50 °C (-4 to 122 °F) | |
| Sound power level | 26.8 dBA, with uncertainty 2.5 dBA | |
| Sound pressure level | 18.8 dBA, with uncertainty 2.5 dBA | |
| Shelf life | 5 years | |
| Materials | Component | Material |
| | Seal | Silicone (LSR) / Nylon (PA) |
| | Frame | Nylon (PA) |
| | Headgear | Nylon (PA) / Pebax (PEBA) |
| | Backstrap | Nylon Spandex / UBL / Foam |
| | Tube | Polypropylene (PP) |
| | Swivel | Nylon (PA) |
| | Masks and accessories are not made with natural rubber latex. | |
| Biocompatibility | Meets standards: ISO 10993-1:2018, ISO 18562-1:2017 | |
| Packaging materials | Outer box: Corrugated fibreboard box | Inner bag: Polyethylene/Polyester laminate |
| Packaging dimensions (mm) | Outer box: 444 X 335 X 226 mm (L x W x H) | Inner bag: 341 X 274 mm (L x W) |
| Disposal | Mask does not contain any hazardous materials and may be disposed of with general waste | |

| Regulatory | | |
|---------------------|---|---------------|
| Classification | USA - Class II; EU - Class IIa, Australia - Class IIa | |
| Country of origin | Made in New Zealand and Mexico | |
| GMDN Code | 57815 | |
| CE marking | CE0123 | |
| EU Notified Body | TÜV 0123 - Product Service GMBH | |
| Product Order Codes | | |
| Code | Description | |
| EVO1SU | Evora Nasal Mask Small U Model | |
| EVO1MU | Evora Nasal Mask Medium U Model | |
| EVO1LU | Evora Nasal Mask Large U Model | |
| EVO1WU | Evora Nasal Mask Wide U Model | |
| EVO1SSU | Evora Nasal Mask Double Seal - Small Small U Model* | |
| EVO1MMU | Evora Nasal Mask Double Seal - Medium Medium U Model* | |
| EVO1LLU | Evora Nasal Mask Double Seal - Large Large U Model* | |
| EVO1SMLU | Evora Nasal Mask Fit Pack - Small, Medium, Large U Model* | |
| Spare Parts | | |
| Code | Description | |
| 400EVO111 | Evora Nasal Seal Small Spare | |
| 400EVO112 | Evora Nasal Seal Medium Spare | |
| 400EVO113 | Evora Nasal Seal Large Spare | |
| 400EVO114 | Evora Nasal Seal Wide Spare | |
| 400EVO121 | Evora Nasal Headgear Spare | |
| 400EVO122 | Evora Nasal Backstrap Spare | |
| 400EVO171 | Evora Nasal Frame and Tube Spare | |
| 400FPH341 | F&P Swivel White | |
| GTIN | | |
| Code | Each | Box |
| EVO1SU | 9420012456267 | 9420012459947 |
| EVO1MU | 9420012456274 | 9420012459954 |
| EVO1LU | 9420012456281 | 9420012459961 |
| EVO1WU | 9420012456298 | 9420012459978 |
| EVO1SSU | 9420012456366 | 9420012460042 |
| EVO1MMU | 9420012456373 | 9420012460059 |
| EVO1LLU | 9420012456380 | 9420012460066 |
| 400EVO111 | 9420012456489 | 9420012460165 |
| 400EVO112 | 9420012456496 | 9420012460172 |
| 400EVO113 | 9420012456502 | 9420012460189 |
| 400EVO114 | 9420012456519 | 9420012460196 |
| 400EVO121 | 9420012456526 | 9420012460240 |
| 400EVO122 | 9420012456533 | 9420012460257 |
| 400EVO171 | 9420012458995 | 9420012460288 |
| 400FPH341 | 9420012456540 | 9420012460271 |

Always refer to the instructions for use supplied with the product for a full list of instructions, warnings, contraindications and explanations. Some products mentioned may not be available in your region.