



WIZARD 510

Nasal Mask

Clinical Practice Guideline

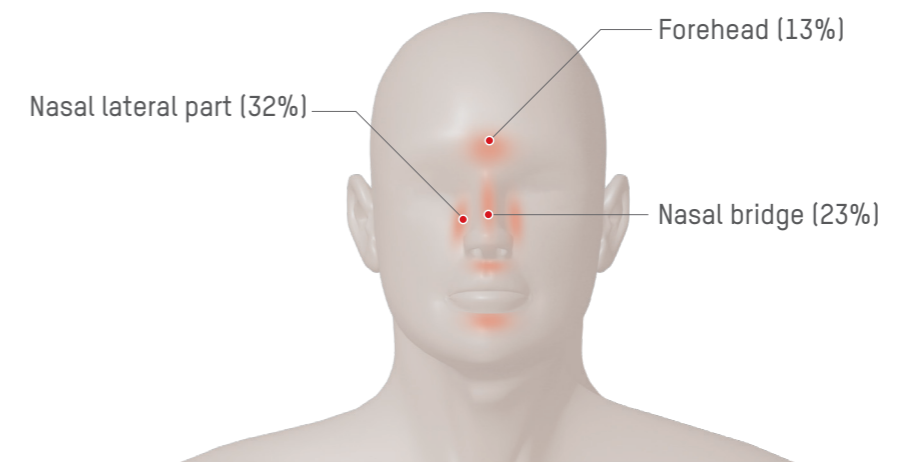
Minimum Contact Nasal Mask- WIZARD 510

Apex has launched WIZARD 510 Nasal Mask, which provides an interface for Continuous Positive Airway Pressure (CPAP) or Bi-level Positive Airway Pressure (BiPAP) therapy. WIZARD 510 Nasal Mask is designed for adult patients greater than 30 (kg) for whom positive airway pressure (CPAP or BiPAP system) has been prescribed. WIZARD 510 Nasal Mask is intended for single-patient reuse at home and multi-patient, multi-use in the hospital environment under the correct clean and disinfection procedure.

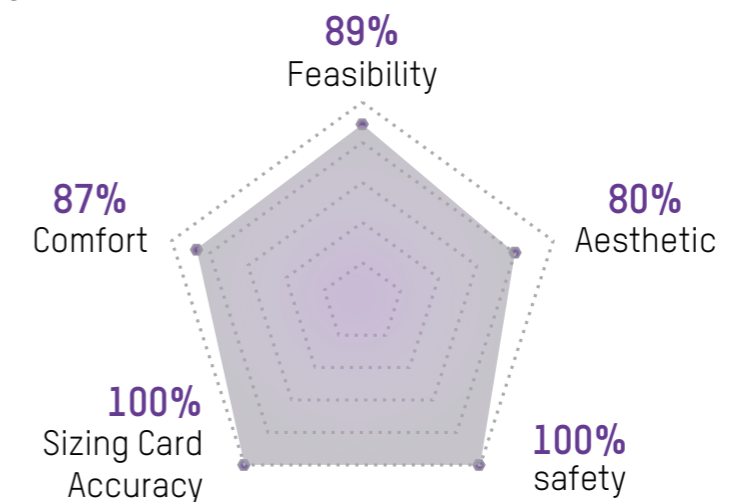
Featuring with minimum contact, there is no forehead pad in WIZARD 510 Nasal Mask to touch the forehead and to cause excessive pressure on the nose bridge, but it still offers solid stability and comfort to our patients. They can wear glasses while wearing the WIZARD 510 Nasal Mask without any view obstruction. The minimum level of contact of WIZARD 510 Nasal Mask weighs only 93(g) for S/M size cushion and 95(g) for L size cushion to allow patients feel free and comfortable at every direction.

The Reported Complaint of Traditional Nasal Mask

Reportedly, the discomfort and complications of wearing traditional Nasal Mask may affect patients' compliance; the most frequent pain spots includes pressure ulcer on nasal bridge (23%), nasal lateral part (32%) and forehead (13%). Besides, 15% of interviewees are not satisfied with the use of CPAP while wearing glasses and 18% of them are disturbed by the strap and eyes irritation by the air leaking from the poor fitting cushion¹.



According to the internal survey by Apex², high satisfaction of WIZARD 510 Nasal Mask has been proved. The accuracy of sizing card provides 100% satisfaction to ensure patients a proper way to fit WIZARD 510 Nasal Mask with ease. The safety of WIZARD 510 Nasal Mask is verified that there is no concern about noise or other health issues, such as dry throat and headache. The degree of satisfaction of feasibility, aesthetic and comfort of WIZARD 510 Nasal Mask all above 80% according to the survey. Our patients obtain an effective and enjoyable treatment experience as well as a restful sleep after using it.



WIZARD 510 Nasal Mask

"Comfortable at every direction"

Easy Assembly



Quick Snap-on
Assemble the mask promptly and easily for replacement and cleaning

Tranquil Fresh Tech

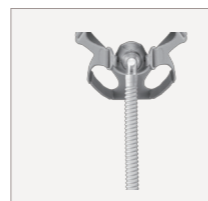
Brand new technology¹² on exhalation port decreases turbulent flow to decrease CO₂ rebreathing, eliminating noise and provides quiet sleeping environment

Buckle-off Headgear Clips



A buckle-off design is for a quick release of the headgear

Contour Fitting Cushion

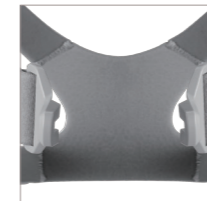


The ergonomic cushion with multi-pressure redistributed design provides comfortable facial support to our patients

3D-shaped Headgear



Simple Wearing
Simple putting on and taking off design makes therapy setting trouble-free



Breathable Headgear
Breathable and durable material gives comfortable experience

Wider Visibility Design

Open field of vision without sight obstruction and forehead pad delivers convenience to patients, so they can comfortably read or watch TV in bed while the therapy is ongoing

Skin-Friendly Side Frame

Soft fabric side frame reduces red mark on the cheeks and provides comfortable sleep, especially for side-sleepers

3D-Shaped Headgear

Maintain both firm seal and comfort fitting

Convenient Tubing System



Quick-Released Swivel
One hand to disconnect the tube by the swivel



Flexible Connection Tubing
Easy to move during sleep

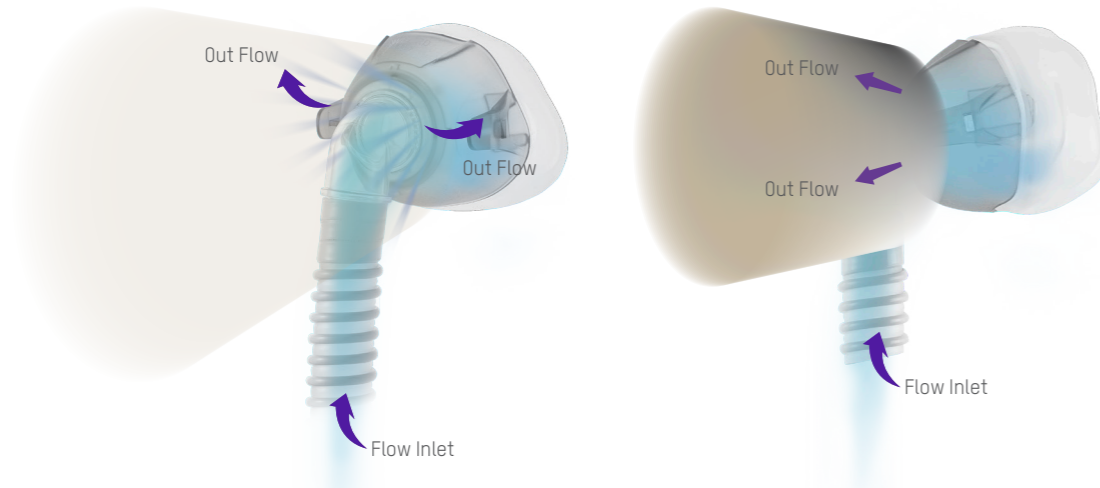
Tranquil Fresh Tech

Brand new technology¹² on exhalation port decreases turbulent flow to decrease CO₂ rebreathing, eliminating noise and providing quiet sleeping environment.



“Rebreathing has been defined as occurring when CO₂ in mixed expired gas is greater than that expected from the reinhalation of anatomical deadspace gas”³. A defective designed mask is at a risk of hypercapnia (high concentration of CO₂ in the blood) which may cause headaches, dizziness, having difficulty in breathing, and abnormal tiredness⁴.

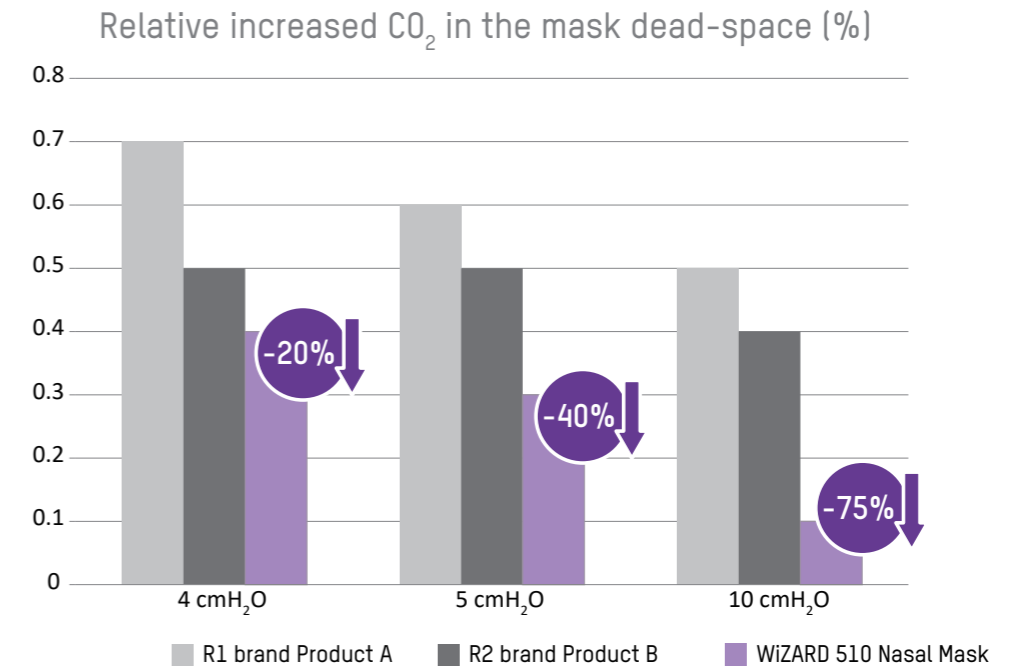
As hypercapnia might be caused by an inappropriate design of vent port of masks for patients using CPAP and BiPAP devices, APEX has been dedicating in developing novel technology “Tranquil Fresh Tech” boosting the efficacy and performance of WIZARD 510 Nasal Mask.



“Tranquil Fresh Tech” in WIZARD 510 Nasal Mask features lower turbulent flow and separated inhaling flow and exhaling flow in order to eliminate annoying noise and reduce expiratory resistance. Thanks to this novel technology, it helps our patients and their sleep partner to obtain a tranquil, peaceful sleep and receive the effective treatment.

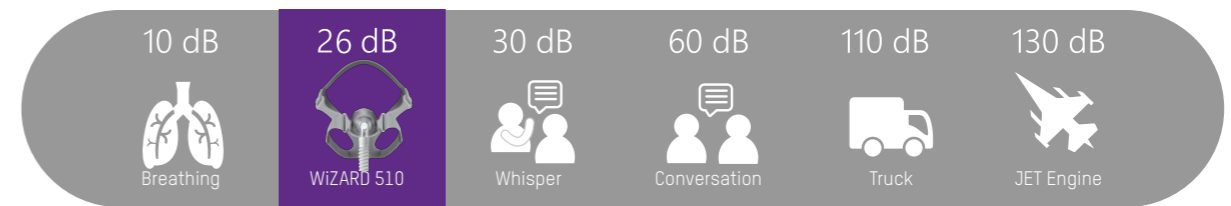
Meanwhile, the WIZARD 510 Nasal Mask aims to provide adequate ventilation and expel CO₂ efficiently from exhalation ports. The results of relative increased CO₂ in mask deadspace reveal that the residual CO₂ in WIZARD 510 Nasal Mask is lower than other brands of nasal masks.

“Tranquil Fresh Tech” of WIZARD 510 Nasal Mask, therefore, can significantly prevent CO₂ rebreathing issue which is verified by EN ISO 17510 : 2020 and also provide our patients a refreshing feeling in the morning.



! This figure is made and shown based on the content of test results from from an independent certifying authority. Apex shall not be responsible for the authenticity and accuracy for any figure and content in this figure and shall not be responsible for any action or omission of any party based upon the content of this figure.

Furthermore, the sound level of WIZARD 510 Nasal Mask is examined in an anechoic chamber based on ISO 3744 and it revealed a great result due to this technology. It is foreseeable to provide an quiet and restful therapy experience for patients wearing this mask.



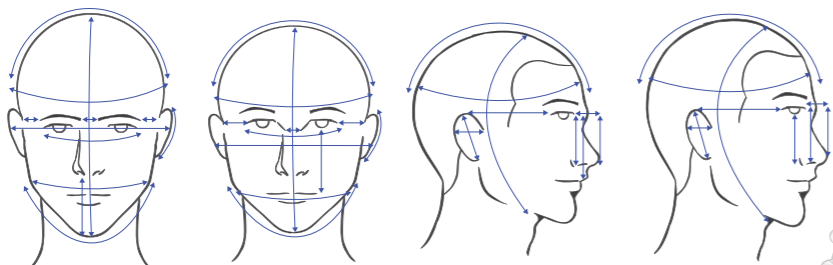
3D-shaped Headgear

Ease of Use and Comfortable Fitting

The comfort and stability of headgear should be emphasized in order to accomplish patients' requirement and decrease disadvantages of wearing mask clinically⁵. Besides, the comfort and stability of headgear are also one of key factors that may affect CPAP patients' treatment compliance¹.

According to the literature, 18% of patients are not satisfied with the headgear straps which may cause red marks on their faces after waking up in the morning and feel uncomfortable. 38% of interviewees agreed with the statement that the design of straps should increase the capability of proper fitting and adjustment¹.

In order to seek solutions of designing suitable headgears to CPAP patients who possess different structural head features, APEX has reviewed head anatomical features related literatures and invents this 3D-shaped headgear to diminish the gap of design between different head sizes of different races⁶.



The 3D headgear of WiZARD 510 Nasal Mask features the following characteristics: Simplicity of wearing method, stability regardless of the sleeping positions, and the comfortable touch of fabric headgear design.

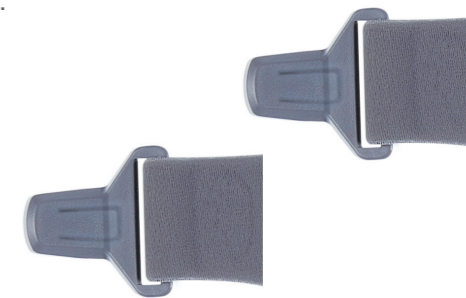
The skin friendly side-frame of WiZARD 510 Nasal Mask allows side-sleepers to enjoy a restful sleep without leaving red marks on face and to benefit from stable support every night. It is proved that the headgear of WiZARD 510 Nasal Mask can provide a wide coverage of head size which would not be limited to different races or genders.



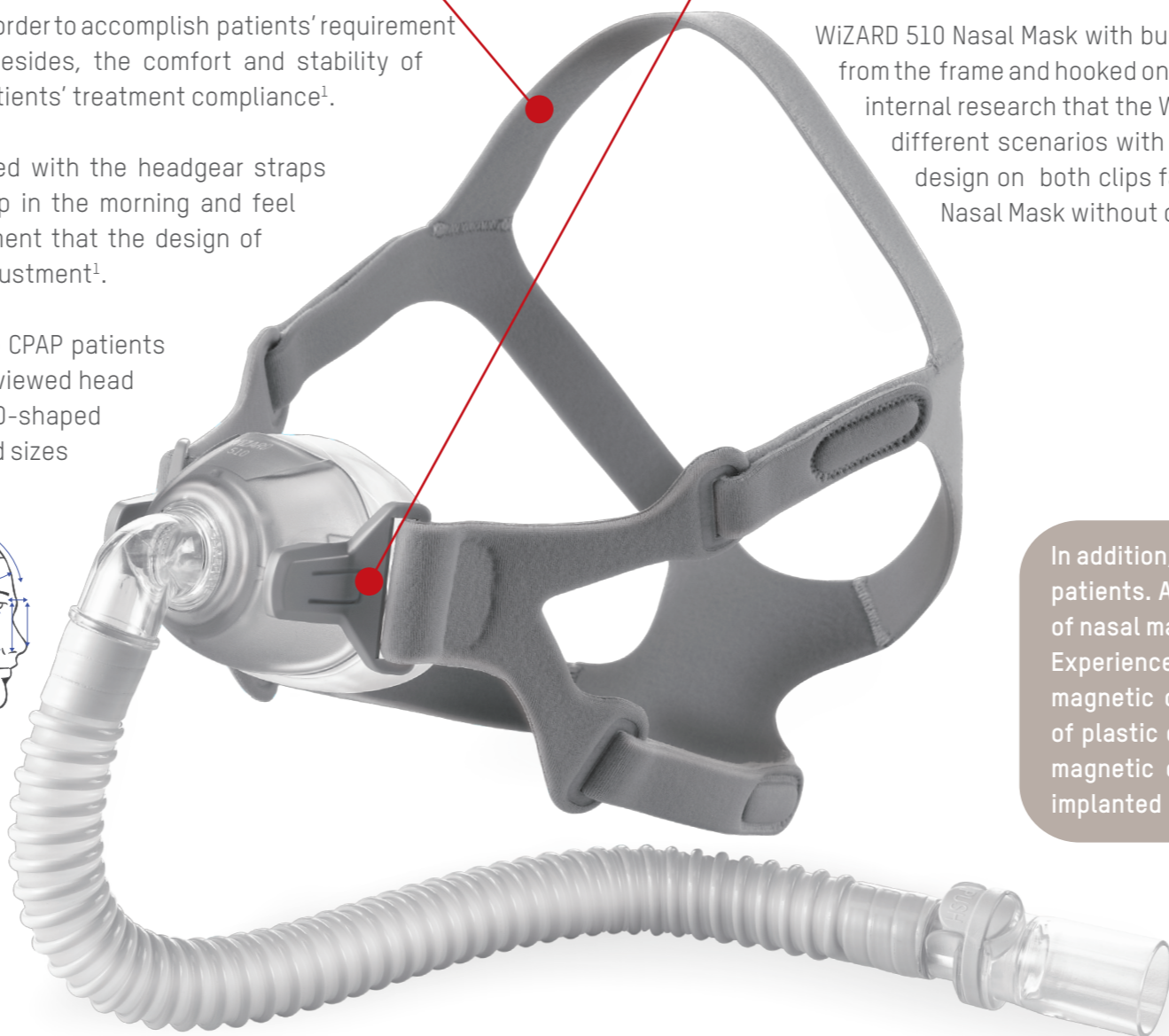
Buckle-off Headgear Clips

Easy clip, easy fit

WiZARD 510 Nasal Mask with buckle-off designed clips can be quickly released from the frame and hooked on without extra effort. It has been proven in Apex's internal research that the WiZARD 510 Nasal Mask can be operated easily in different scenarios with different usage habits. Moreover, the intuitive design on both clips facilitates patients to assemble the WiZARD 510 Nasal Mask without confusion.



In addition, Apex cares for a healthy life and values the health of all OSA patients. Apex has reviewed the adverse events by using other brands of nasal masks from U.S. FDA and Manufacturer and User Facility Device Experience (MAUDE). Considered the adverse events associated with magnetic clips of CPAP mask, WiZARD 510 Nasal Mask is composed of plastic clips and other brilliant details mentioned above. The non-magnetic clips can prevent the interference to other medical aids implanted in the chest or the brain to avoid potential risks.

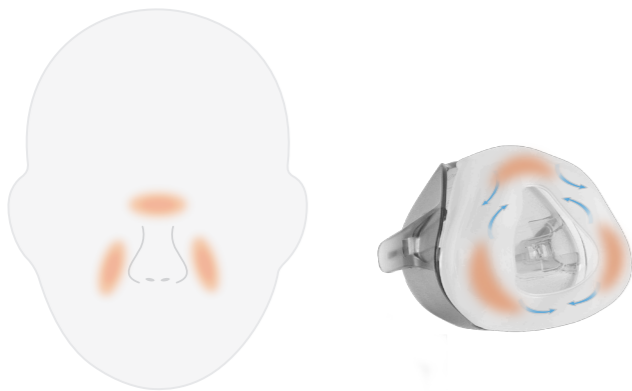


Contour Fitting Cushion

Multi-pressure redistributed design increases your comfort level!

Pressure sores are a frequent complication in the acute NIV settings, affecting 10-31% of patients⁷. Since the first case report in which a reverse event of skin necrosis was caused by CPAP mask in 1993⁸, scientists and manufacturers have been working for comfortable and durable mask cushion design.

The dilemma of mask design is the balance between comfort and stability of masks. In terms of wearing the mask steadily on the face for all night without air leaking, providing a comfortable experience without sensing the existence of the mask is rather difficult. In addition, being imposed higher levels of respiratory pressure, patients will be likely to fit mask more tightly so that air-leaks can be prevented. However, this action may lead to a higher risk of developing skin lesions⁷.



Apex has studied human facial anatomical features and developed the ergonomic cushion with multi-pressure redistributed design in two sizes (S/M and L) to fit the contour nuances on human faces. WiZARD 510 Nasal Mask is able to preclude the possibility of pressure injury by redistributing the pressure while applying on fragile and sensitive facial parts, such as nose bridge and lips.

Easy Assembly

Regular cleaning is the first step to long durability of a mask!



In order to extend the usage period and maintain the excellent usage experience, cleaning a CPAP mask frequently and properly is a key to the success. The soft silicon cushion of WiZARD 510 Nasal Mask is integrated with a plastic part to assemble and disassemble with the plastic mask frame easily and intuitively.

WiZARD 510 Nasal Mask is made of three parts: cushion, headgear with clips and mask frame with tubing system. These three components can be assembled and disassembled easily for cleaning or replacing cushions for different sizes.

Three parts of WiZARD 510 Nasal mask can be washed separately. The clean procedure and disinfection guide, including physical and chemical disinfection methods, are detailed in WiZARD 510 Nasal Mask User Manual.

Convenient Tubing System

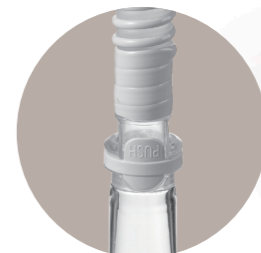
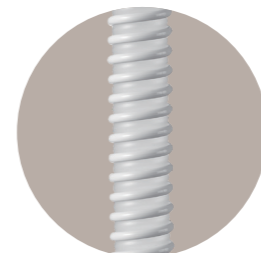
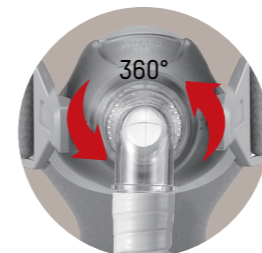
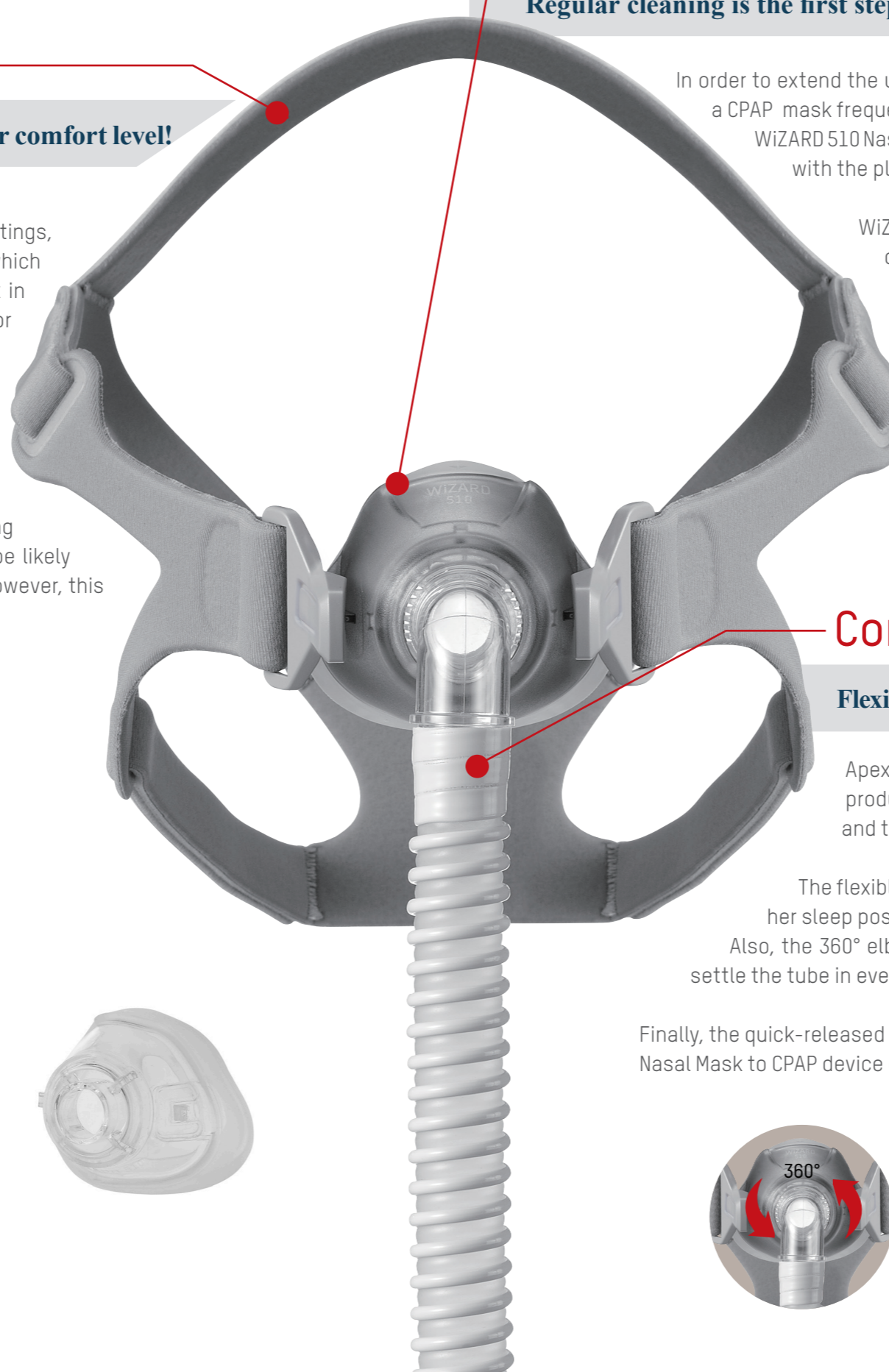
Flexible tube design offers you to toss and turn easily and smoothly

Apex has been trying to optimize the tubing system to enhance the product performance, which includes the tube elbow, the soft tube and the quick-release swivel, of WiZARD 510 Nasal Mask.

The flexible connecting tube can be adjusted while patient changes his/her sleep positions without dragging or entangling the tube.

Also, the 360° elbow between mask frame and tube offers patients freedom to settle the tube in every direction.

Finally, the quick-released swivel assists patients to disconnect and connect WiZARD 510 Nasal Mask to CPAP device easily when going to restroom at night.



Technical Specifications⁹⁻¹¹

Note: The mask system does not contain latex, PVC or DEHP materials.

Exhaust Flow	The mask has vent holes to protect against rebreathing.								
Pressure (cm H ₂ O)	4	8	12	16	20	24	28	30	
Flow (L/Min)	20	29	37	43	49	54	59	61	

Mask Dead Space	M 75.3 ml	L 93.6 ml
Therapy Pressure Range	4-30 cmH ₂ O	
Resistance (pressure drop)	at 50 l/min: 0.4 cmH ₂ O	
Sound Level	26 dBA (with CAPA and humidifier) / 28 dBA (with CPAP) (Pressure setting 10cmH ₂ O, at 1 meter position)	

Disinfection Guide

Physical Disinfection (Pasteurization)

76°C(168.8F) : 30 min

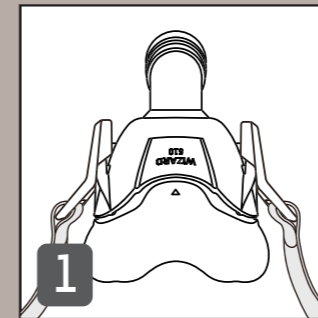
Chemical high level disinfection

Cidex OPA (0.55%) ortho-phthaladehyde: 12 min soaking temperature: 20°C (68°F)

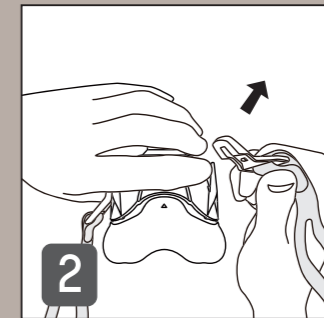
CAUTIONS

- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilization.
- When using detergents, disinfectants or sterilization agents, always follow the manufacturer's instructions.
- Do not iron the headgear as the material is heat sensitive and will be damaged.
- Please read the user manual of WiZARD 510 Nasal Mask for detailed information of Technical Specifications and Disinfection Guide.

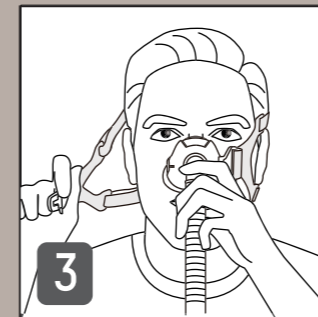
WiZARD 510 Wearing Steps



Hold the mask with cushion toward your body and WiZARD 510 facing up.



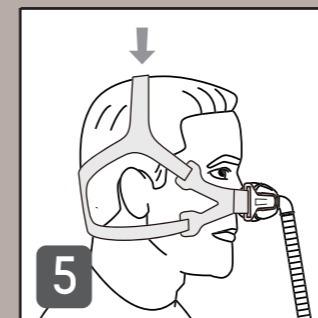
Hold the mask by the top and bottom of the frame. Hold the fabric strap by your thumb and pull the buckle outward to release.



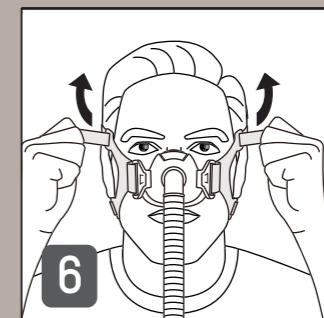
Put on the headgear across your head with cushion attaching over your nose.



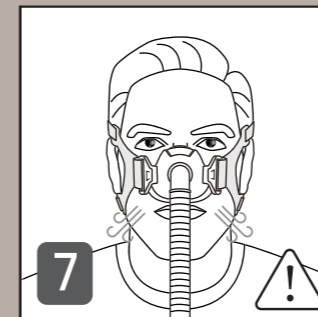
Hook on the buckle backwards along your face.



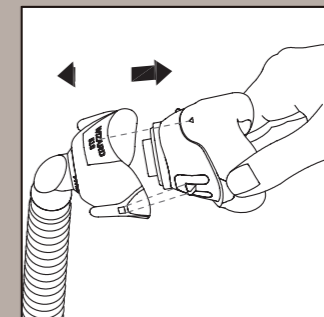
Adjust the straps to fit the headgear properly. The cushion should lightly touch your face.



Adjust the velcro types on both side evenly to tighten the headgear comfortably.



If necessary, slightly adjust the cushion to get a better sealing and avoid air leakage.



To replace the cushion, pull or push directly with arrow aligning with WiZARD 510 on the frame.

FAQ

1. What is the suitable pressure range for this WiZARD 510?

4-30 cmH₂O

2. What kinds of machines are applicable to this WiZARD510 Nasal Mask?

This applies to most models of CPAP or bi-level device.

3. Should I buy the whole mask if I lose or break one of mask components?

Not necessary to replace the whole mask just for one component. We provide cushion, headgear with clips and mask frame with tubing system for you to purchase.

4. How often should I clean my mask? Any cleaning instructions?

We would suggest you to clean your cushion daily without headgear after each use and wash headgear weekly. Please refer to the user manual for the further instructions.

5. If my head is really small and I still have some extra length for upper headgear, where should I stick it?

We would suggest you to stick the extra upper headgear upwards to the top strap.

6. Can I bring this mask to go traveling?

Sure! The weight of WiZARD 510 is less than 95 (g) which is really light and easy to carry.

7. Is it allowed to have some leakage from the mask when I wear it? Should I tighten it to reduce the leakage?

Please do not overtighten the strap otherwise it may make you feel uncomfortable. It is ok to have minimal leakage and APEX's CPAP machines have leak compensation mechanism to help you.

8. I'm allergic to latex so can I use this WiZARD 510 mask?

Yes, no problem. The material of WiZARD 510 mask does not contain latex, PVC or DEHP materials and it has been verified by ISO 10993 biocompatibility test.

9. Any warranty for this mask?

Yes, we provide 6 months warranty under normal cleaning procedures which are mentioned in the user manual.

10. Can I use dishwasher to clean my headgear?

Unfortunately, the high temperature mode of dishwashers may damage the material of headgear. Please refer to the user manual for the further instructions.

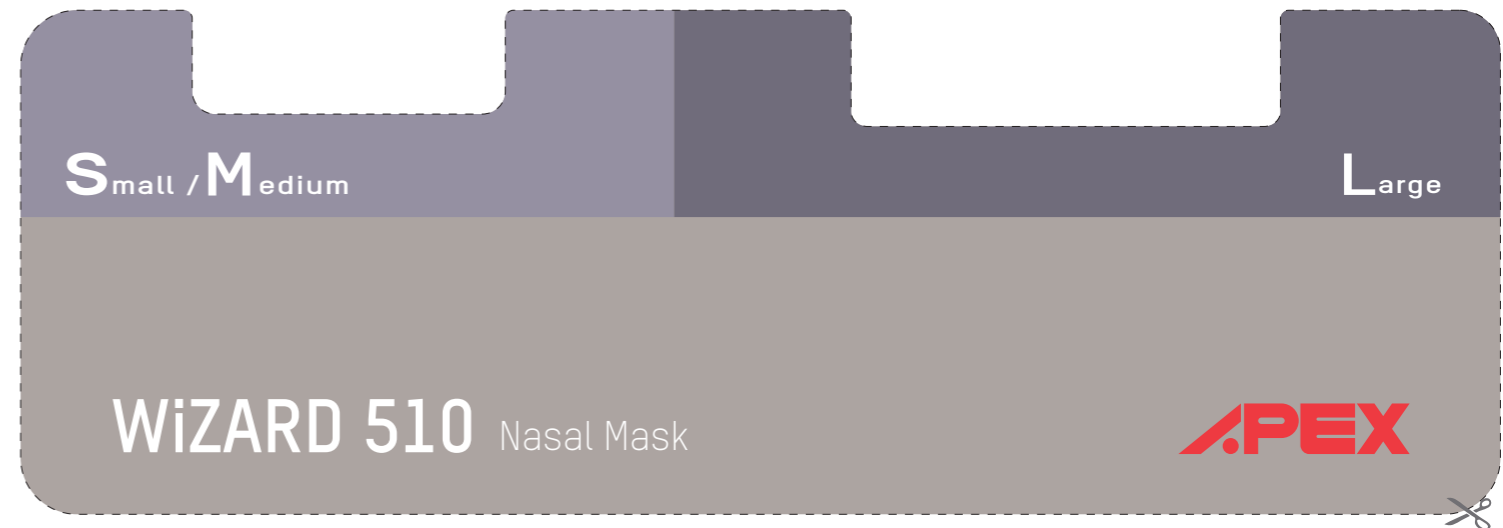
11. How do I measure my cushion size?

Apex provides two sizes: S/M and L. Please refer to the Fitting Gauge to find your size correctly.

Fitting Gauge

WiZARD 510 Nasal Mask provides cushions with two sizes : S/M and L. The Small/Medium cushion comes ready to use and is the average size. You'll have to switch in the large cushion if necessary.

Please print it out to measure the size.



Ruler is for scaling purposes

Inch



CM



References

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8. SMURTHWAITE, G. and FORD, P., 1993. Skin necrosis following continuous positive airway pressure with a face mask.
9. The exhaust flow and resistance (pressure drop) are in accordance with ISO 17510.
10. The mask dead space is verified by Apex internal test and simulated by computer graphics software Pro/E.
11. The sound level is in accordance with ISO 3744.
12. Patent pending in Taiwan (107132543), US (16/563966), Europe (EP19196190.3) and China (201910847286.X).

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